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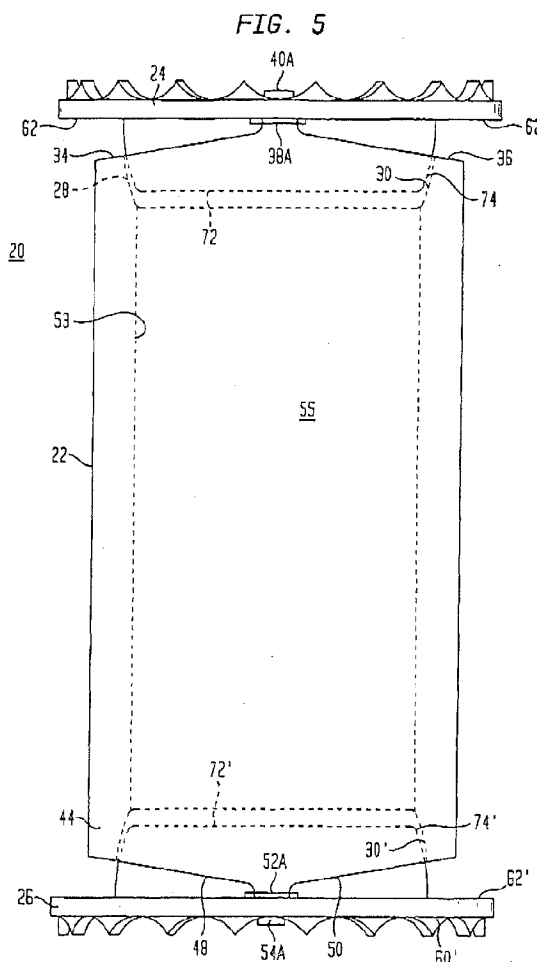
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(54) Vertebral body spacer having variable wedged endplates

(57) A vertebral body spacer (20) includes a main body (22) having an upper end (28) including a first concave socket (30) and a lower end (44) including a second concave socket (45), a first endplate (24) secured to the upper end (28) of the main body, the first endplate (24) including an underside (62) having a convex projection (72) adapted to form a ball and socket arrangement with the first concave socket (30), and a second endplate (26) secured to the lower end (44) of the main body (22), the second endplate (26) including an underside (62') having a convex projection (72') adapted to form a ball and socket arrangement with the second concave socket (30').



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Description

BACKGROUND OF THE INVENTION

[0001] The present invention is related to orthopedic implants and is more particularly related to spinal implants.

[0002] There have been many efforts directed to providing improved spinal implant devices. For example, U. S. Patent 5,534,029 to *Shima* discloses an articulated vertebral body spacer including a pair of upper and lower joint pieces inserted between opposing vertebrae. The lower joint piece includes a convex portion formed on a central portion of its upper surface and having a convex sliding contact surface, and a stopper surface surrounding the convex portion. The upper joint piece includes a concave portion formed on a central portion of its lower surface and having a concave sliding contact surface which is in sliding contact with the convex sliding contact surface, and an abutment surface that surrounds the concave portion and abuts against the stopper surface. A cavity for allowing the upper joint piece to pivot in response to movement of the opposing vertebral bodies is formed between the abutment surface and the stopper surface.

[0003] DE 3529761 discloses in FIGS. 1A and 1B thereof a prosthesis for an intervertebral disc including two plates 1 with a spacer disc 4 therebetween. The two plates 1 each have a concave center and a flat annular rim 2 with spikes 3. The disc spacer 4 has a convex center and a flat rim with an annular groove 6. The prosthesis is used for spanning the gap between opposing vertebral faces remaining firmly in place while permitting natural movement of the spine.

[0004] U.S. Patent 4,997,432 to *Keller* discloses a prosthesis including two stop plates 3 and a sliding body 4 arranged therebetween. The outer surfaces of the stop plates 3 have an essentially planar surface 5 provided with tooth-like projection 6 that penetrate into the vertebral bodies to fix the stop plates 3 securely to the vertebral bodies 1. The opposite side surfaces of the stop plates 3 include essentially spherical-shell-shaped recesses 7. The sliding core 4 has a spherical-shell-shaped projections 8 corresponding to the spherical-shell-shaped recesses 7. The stop plates 3 are made of metal and the sliding body 4 is made of a synthetic material.

[0005] U.S. Patent 5,562,738 to *Boyd et al.* discloses an implant device 110 having an ellipsoidally-shaped ball 146 and socket 126 oriented so that their greatest lengths are disposed along a first axis transverse to the anterior and posterior ends 158 and 160 respectively and their shortest lengths are disposed along a second axis which is perpendicular to the first axis along surface 156. A first joint surface 136 is sloped away from socket 126 while a second joint surface 156 remains flat. The degree of slope determines the amount of relative rotation between joint surfaces 136 and 156 respectively,

and the first joint surface 136 is sloped to provide for up to 5° of lateral bending in either direction, up to 5° of extension and up to 5° of Flexion.

[0006] Finally, U.S. Patent 5,556,431 to *Buttner-Janz* discloses an intervertebral disc endoprosthesis that is inserted between two vertebrae and has a bottom plate and a top plate that are connected to vertebral endplates. Referring to FIG. 1, the device includes prosthesis plates 1 and 2 and prosthesis core 3 cooperated via spherical surfaces 4. The core 3 has an edge rim 5 that limits its range of movement and insures, even under extreme conditions cohesion of the prosthesis. The endplate 6 of the prosthesis plates 1, 2 lie on the end surfaces of the vertebrae and are provided with teeth 7 which, under load, penetrate into the vertebrae and thus secure the prosthesis in situ. Bore holes 8 are arranged symmetrically on both side of the central plane, running from ventral to dorsal, of the vertebrae and in the area of the front edge of the prosthesis plates 1, 2 to receive bone screws 9.

[0007] In spite of the above-noted advances in the art, there remains a need for an improved vertebral body spacer having enhanced stabilization and bone fusion characteristics. There is also a need for a vertebral body spacer that may be readily packed with bone growth material for facilitating fusion of the spacer with vertebral bodies. In addition, there is a need for a vertebral body spacer that is capable of obtaining a locking effect without the need for additional components such as locking screws.

SUMMARY OF THE INVENTION

[0008] In certain preferred embodiments of the present invention, a vertebral body spacer includes a main body having an upper end including a first concave socket and a lower end including a second concave socket. A first endplate is secured to the upper end of the main body and includes an underside having a convex projection adapted to form a ball and socket arrangement with the first concave socket. A second endplate is secured to the lower end of the main body and includes an underside having a convex projection adapted to form a ball and socket arrangement with the second concave socket.

[0009] In certain preferred embodiments, the upper end of the main body may include an upper edge defining first and second planes that are angled relative to one, and the lower end of the main body may include a lower edge defining first and second planes angled relative to one another. The first and second planes of the upper edge preferably intersect one another at an upper end apex and the first and second planes of the lower edge preferably intersect one another at a lower end apex.

[0010] The upper apex desirably includes at least one retaining clip projecting therefrom for securing the first endplate to the upper end of the main body and the lower

apex includes at least one retaining clip projecting therefrom for securing the second endplate to the lower end of the main body. In highly preferred embodiments, the upper apex includes a pair of retaining clips spaced from one another for pivotally securing the first endplate and the lower apex includes a pair of retaining clips spaced from one another for pivotally securing the second endplate. The first and second angled planes of the upper edge preferably limit pivotal movement of the first endplate and the first and second angled planes of the lower edge limit pivotal movement of the second endplate.

[0011] In certain preferred embodiments, the first endplate includes an upper side having teeth for engaging bone, such as the face of a vertebral body, and the second endplate includes an upper side having teeth for engaging bone. The first endplate also preferably has a central opening and a peripheral flange surrounding the central opening, the peripheral flange having at least one opening adapted to facilitate bone fusion. The second endplate, which may be substantially similar in size and shape as the first endplate, also preferably has a central opening and a peripheral flange surrounding the central opening, the peripheral flange having at least one opening adapted to facilitate bone fusion.

[0012] Each endplate preferably includes at least one retaining clip aperture adapted for receiving one of the retaining clips for securing the endplate with the main body.

[0013] In certain preferred embodiments, the main body is elongated and has an outer surface that is curved. In other preferred embodiments, the main body is substantially cylindrical in shape. The main body may also be elliptical, or have any other geometric shape. In one particular preferred embodiment, the main body has a longitudinal axis and the first and second concave sockets are coaxial about the longitudinal axis. The first and second angled planes at the upper end of the main body form an angle of approximately 5-25 degrees, and more preferably an angle of approximately 10-20 degrees. The main body desirably has a cross-sectional diameter of approximately 10-30 mm, and the endplates have a diameter of approximately 30-50 mm. In other preferred embodiments, the endplates have a diameter of approximately 35-40 mm.

[0014] The main body and the first and second endplates are desirably made of biocompatible materials, such as titanium, stainless steel, alloys and combinations thereof. The biocompatible material may also comprise polymeric materials.

[0015] The central opening of the first endplate desirably provides communication between the first socket and an exterior of the spacer. The central opening of the second endplate desirably provides communication between the second socket and an exterior of the spacer.

[0016] In operation, the spacer is positioned between the opposing faces of vertebrae. The endplates are pivotable when the spacer is in a first no-load state and are locked from pivotal movement when the spacer is in a

second load state. Once pressure is applied to the endplates, the ball-and-socket joints are locked due to the blockage of the convex projections of the endplates in the concave sockets. After being positioned between two vertebrae, the endplates are desirably oriented for pivoting in a sagittal plane of a spine,

[0017] In other preferred embodiments of the present invention, a vertebral body spacer includes a main body having an upper end and a lower end, the upper end having a first concave socket and an upper edge surrounding the first concave socket defining first and second planes angled relative to one another, the lower end having a second concave socket and a lower edge surrounding the second concave socket defining first and second planes angled relative to one another. The spacer also preferably includes a first endplate pivotally secured to the upper end of the main body for pivoting between the first and second planes of the upper edge, the first endplate including an underside having a convex projection adapted to engage the first concave socket. The spacer also preferably includes a second endplate pivotally secured to the lower end of the main body for pivoting between the first and second planes of the lower edge, the second endplate including an underside having a convex projection adapted to engage the second concave socket. The convex projections preferably form ball and socket joints with the respective first and second concave sockets.

[0018] The upper edge desirably includes at least one retainer clip projecting therefrom for pivotally securing the first endplate to the main body, and the first endplate desirably includes at least one retainer clip aperture extending therethrough, the at least one retainer clip being passable therethrough for pivotally securing the first endplate to the main body. The first endplate preferably includes a series of apertures extending therethrough for receiving bone growth material and facilitating spinal fusion.

[0019] The lower edge desirably includes at least one retainer clip projecting therefrom for pivotally securing the second endplate to the main body, and the second endplate desirably includes at least one retainer clip aperture extending therethrough, the at least one retainer clip being passable therethrough for pivotally securing the second endplate to the main body. The second endplate preferably includes a series of apertures extending therethrough for receiving bone growth material and facilitating spinal fusion.

[0020] These and other preferred embodiments of the present invention will be described in more detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021]

FIG. 1 shows a perspective view of a vertebral body spacer including a main body, a first endplate and a second endplate.

FIG. 2 shows a perspective view of the main body of FIG. 1 with the first and second endplates detached from the main body.

FIG. 3 shows a top view of the first endplate shown in FIG. 1.

FIG. 4 shows an underside view of the endplate shown in FIG. 3.

FIG. 5 shows a side elevation view of the vertebral body spacer of FIG. 1.

FIG. 6 shows a partial cut away view of the vertebral body spacer of FIG. 5.

FIG. 7A shows the first endplate of FIG. 1 under a no-load condition.

FIG. 7B shows the first endplate of FIG. 7A under a load condition.

FIG. 8A-8C show the vertebral body spacer of FIG. 5 with the first and second endplates pivoted to various angles relative to the main body.

DETAILED DESCRIPTION

[0022] FIG. 1 shows a vertebral body spacer in accordance with certain preferred embodiments of the present invention. The spacer 20 includes a main body 22 having a first endplate 24 secured to an upper end of the main body and a second endplate 26 secured to a lower end of the main body. The spacer 20 is preferably made of a biocompatible material, such as a polymeric material, titanium, or stainless steel. Preferred materials may also include titanium alloys or stainless steel alloys. Referring to FIG. 2, in certain preferred embodiments, main body 22 has a longitudinal axis designated A-A. Main body 22 is preferably substantially cylindrical in shape and has an exterior surface that is coaxial with longitudinal axis A-A. In other preferred embodiments, main body 22 may be polygon-shaped in cross section. Main body 22 may have any geometric shape, such as the shape of an oval or ellipse. Main body 22 preferably has an upper end 28 with a first substantially concave-shaped socket 30 formed therein. The upper end 28 includes an upper edge 32 that surrounds the first concave socket 30. The upper edge 32 includes a first plane 34 and a second plane 36 that are angled relative to one another. The planes 34, 36 intersect at respective apexes 38A and 38B. Upper edge 32 also includes opposing first and second retaining clips 40A and 40B. First retaining clip 40A has an inwardly extending portion 42A and second retaining clip 40B has an inwardly extending projection 42B. As will be described in more detail below, the retaining clips 40A, 40B are designed to pass through retainer clip openings that extend through the endplates shown in FIG. 1 for securing the endplates to the respective upper and lower ends of main body 22.

[0023] Referring to FIG. 2, main body 22 also has a lower end 44 including a substantially concave socket 45 and lower edge 46 that is substantially similar in design and shape to the first socket 30 at upper end 28.

The lower edge 46 has a first inclined plane 48 and a second inclined plane 50 angled relative to one another, the inclined planes intersecting at opposing retaining clips 54A and 54B that are designed to pass through the retaining clip apertures of the second endplate. Main body 22 includes a substantially cylindrical interior wall 53 defining a hollow space 55 that extends between the upper end cavity 30 and the lower end cavity 45. In other embodiments, the interior wall 53 may be a flat surface or have any geometric shape defining a hollow space inside main body 22. As will be described in more detail below, the hollow space is adapted to receive bone growth material therein for facilitating fusion of the spacer 20 with vertebral bone.

[0024] FIG. 3 shows a top view of the first endplate 24. First endplate 24 includes a central opening 56 surrounded by a peripheral flange 58. Referring to FIGS. 3 and 4, the peripheral flange 58 has an upper surface 60 and a lower surface 62 opposite the upper surface 60. The peripheral flange also includes a series of apertures 64A-C and 66A-C. First endplate 24 also includes retainer clip apertures 68A and 68B that extend between upper and lower surfaces 60, 62 of flange 58. Upper surface 60 also includes a plurality of teeth 70 for anchoring or biting into bone such as the face of a vertebral body.

[0025] Referring to FIG. 4, first endplate 24 also includes a projection 72 extending from an underside 62 thereof. The projection 72 surrounds central opening 56 and has an exterior surface 74 that is substantially curved or convex. As will be described in more detail below, the substantially convex 74 projection facilitates pivotal movement of the first and second endplates 24, 26 relative to main body 22 (FIG. 1) when the endplates are not under load.

[0026] Referring to FIGS. 1 and 5, the vertebral body spacer 20 is assembled by juxtaposing the first endplate 24 with the upper end 28 of main body 22 and the second endplate 26 with the lower end 44 of main body 22. During assembly, the opposing retaining clips 40A, 40B are passed through the retaining clip apertures 68A, 68B (FIG. 3) of first endplate 24. In certain preferred embodiments, the retaining clips 40A, 40B are resilient so as to snap fit in place for pivotally connecting first endplate 24 with main upper end 28 of body 22. After the first endplate 24 has been snap fit in place, the convex exterior surface 74 of projection 72 is preferably in close engagement with first socket 30. As such, first endplate 24 is able to pivot about apex 38A, with the engagement of convex exterior surface 74 and first socket 30 guiding movement of first endplate 24. First endplate 24 is able to pivot in a counterclockwise direction approximately 10° until underside surface 62 engages first plane upper edge 34 and in a clockwise direction approximately 10° until underside surface 62 engages second plane edge 36. Thus, the range of pivotal movement of first endplate 24 relative to upper end 28 of main body 22 is between 15° - 25°.

[0027] In a similar fashion, second endplate 26 is se-

cured to retaining clips 54A, 54B at lower end 44 of main body 22. Second endplate 26 is assembled with main body 22 by passing retaining clips 54A, 54B through retaining clip apertures (not shown) extending between upper surface 60' and underside surface 62'. As second endplate 26 is assembled with lower end 44 of main body 22, convex exterior surface 74' of projection 72' closely engages second socket 30' for guiding pivotal movement of second endplate 26 about apex 52A.

[0028] Second endplate is pivotable approximately 10° in the counterclockwise direction until underside surface 62' engages second plane 50, and approximately 10° in the clockwise direction until underside surface 62' engages first plane 48.

[0029] Referring to FIG. 5, bone growth material (not shown) can be passed through the central openings of the first and second endplates 24, 26 for being disposed in hollow space 55. In certain preferred embodiments, the bone growth material completely fills the hollow space 55 and extends beyond the upper and lower ends 28, 44 of main body 22. In more preferred embodiments, the bone growth material is disposed in the central openings of the endplates 24, 26 for facilitating fusion with opposing vertebral bodies.

[0030] FIG. 6 shows a partially cut-away view of the vertebral body spacer 20 of FIG. 1. As described above, main body 22 includes upper end 28 and lower end 44 remote therefrom. The upper end 28 of main body 22 has a first concave socket 30 formed therein and the lower end 44 has a second concave socket 30' formed therein. In preferred embodiments, the main body 22 is substantially hollow, with the hollow opening extending between first socket 30 and second socket 30'. After first and second endplates 24, 26 have been assembled with the respective upper and lower ends 28, 44 of main body 22, the endplates are free to pivot relative to main body so long as little or no load is placed upon the endplates. When the endplates are placed under load, however, the exterior surfaces 74, 74' of the projections are forced into close engagement with the sockets 30, 45 for locking the endplates in place from further movement.

[0031] FIG. 7A shows a fragmentary view of FIG. 6 before load is placed upon first endplate 24. Even though convex surface 74 of first endplate 24 is in direct contact with first socket 30, the first endplate remains free to pivot relative to first socket 30. Referring to FIG. 7B, after load has been placed upon upper surface 60 of first endplate 24, the convex surface 74 is urged into closer engagement with first socket 30, thereby locking first endplate 24 in place and preventing further pivotal movement of first endplate 24 relative to main body 22. Although not limited by any particular theory of operation, it is believed that once load is placed upon first endplate 24, friction forces lock first endplate from further pivotal movement relative to main body 22. First endplate 24 remains locked from further pivotal movement so long as first endplate remains under load. The sec-

ond endplate 26 (FIG. 5) is also locked from further pivotal movement when under load in a manner similar to that described above for the first endplate 24. The above-described locking action can be attained without the need for additional parts such as locking screws that are typically required in prior art devices.

[0032] Once load has been removed from one of the endplates 24, 26, that particular endplate is once again free to pivot relative to main body 22 so long as it is not under load. Once load is reapplied, however, the endplate will once again be locked in place against further pivotal movement. Such locking and unlocking action will take place repeatedly during the life of the vertebral body spacer of the present invention.

[0033] FIGS. 8A-8C show the range of pivotal movement of the first and second endplates 24, 26 relative to main body 22. In FIG. 8A first endplate 24 rotates in a clockwise direction around apex 38A until underside surface 62 engages second plane 36. Second endplate 26 is pivotable about apex 52A until underside surface 62' engages second plane 50.

[0034] FIG. 8B shows the vertebral body spacer 20 of FIG. 8A with first endplate 24A rotated in a fully clockwise orientation and second endplate 26 positioned equidistant between a fully clockwise rotation and a fully counterclockwise rotation. FIG. 8C shows the vertebral body spacer 20 of FIG. 8B with first endplate 24 fully rotated in a clockwise position and second endplate 26 fully rotated in a clockwise position.

[0035] Although not limited by any particular theory of operation, it is believed that the vertebral body spacer 20 of the present invention will provide an effective spacer between end faces of vertebral bodies. The spacer 20 of the present invention may span a gap present after one or more discs or vertebral bodies have been removed. The teeth 70 of the first and second endplates 24, 26 are designed to bite into the bony end faces of the vertebral bodies for holding the spacer 20 in place. In a first no-load state, when no load is applied to the end faces 24, 26, the end faces are free to pivot relative to the upper end 28 and lower end 44 of main body 22. Once a load is exerted upon either endplate 24, 26, however, the endplates are locked in place from further pivotal movement due to engagement of their convex exterior surfaces 74, 74' with the respective first and second sockets 30, 30'.

[0036] In other preferred embodiments, only one of the ends of the main body may have a pivotable endplate connected thereto, while the other end may be rigid or unmovable.

[0037] Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It is therefore contemplated that numerous modifications may be made to the illustrated embodiments and that other arrangements may be made without departing from the spirit and scope of the

present invention as defined by the appended claims.

Claims

1. A vertebral body spacer comprising:

a main body having an upper end including a first concave socket and a lower end including a second concave socket;
a first endplate secured to said upper end of said main body, wherein said first endplate includes an underside having a convex projection adapted to form a ball and socket arrangement with said first concave socket; and
a second endplate secured to said lower end of said main body, wherein said second endplate includes an underside having a convex projection adapted to form a ball and socket arrangement with said second concave socket.

2. The spacer as claimed in claim 1, wherein said upper end includes an upper edge defining first and second planes angled relative to one another and said lower end includes a lower edge defining first and second planes angled relative to one another.

3. The spacer as claimed in claim 2, wherein said first and second planes of said upper edge intersect one another at an upper end apex and said first and second planes of said lower edge intersect one another at a lower end apex.

4. The spacer as claimed in claim 3, wherein said upper apex includes at least one retaining clip projecting therefrom for securing said first endplate to said upper end of said main body and said lower apex includes at least one retaining clip projecting therefrom for securing said second endplate to said lower end of said main body.

5. The spacer as claimed in claim 4, wherein said upper apex includes a pair of retaining clips spaced from one another for securing said first endplate and said lower apex includes a pair of retaining clips spaced from one another for securing said second endplate.

6. The spacer as claimed in claim 4, wherein said first and second angled planes of said upper edge limit pivotal movement of said first endplate and said first and second angled planes of said lower edge limit pivotal movement of said second endplate.

7. The spacer as claimed in claim 1, wherein said first endplate includes an upper side having teeth for engaging bone and said second endplate includes an upper side having teeth for engaging bone.

8. The spacer as claimed in claim 7, wherein said first endplate has a central opening and a peripheral flange surrounding said central opening, and wherein said peripheral flange has at least one opening adapted to receive bone growth materials

9. The spacer as claimed in claim 8, wherein said second endplate has a central opening and a peripheral flange surrounding said central opening, and wherein said peripheral flange has at least one opening adapted to receive bone growth material.

10. The spacer as claimed in claim 4, wherein each said endplate includes at least one retaining clip aperture adapted for receiving one of said retaining clips for securing said endplate with said main body.

11. The spacer as claimed in claim 1, wherein each said endplate has teeth adapted for anchoring said spacer into bone.

12. The spacer as claimed in claim 1, wherein said main body is elongated and has an at least partially curved outer surface.

13. The spacer as claimed in claim 1, wherein said main body has a longitudinal axis and said first and second concave sockets are coaxial about said longitudinal axis.

14. The spacer as claimed in claim 1, wherein said main body and said first and second endplates are made of biocompatible material.

15. The spacer as claimed in claim 14, wherein said biocompatible material is selected from the group consisting of titanium, stainless steel, alloys and combinations thereof.

16. The spacer as claimed in claim 14, wherein said biocompatible material comprises polymeric materials.

17. The spacer as claimed in claim 9, wherein said central opening of said first endplate provides communication between said first socket and an exterior of said spacer.

18. The spacer as claimed in claim 9, wherein said central opening of said second endplate provides communication between said second socket and an exterior of said spacer

19. The spacer as claimed in claim 1, wherein said endplates are pivotable when said spacer is in a first no-load state and are locked from pivotal movement when said spacer is in a second load state.

20. The spacer as claimed in claim 2, wherein said first

and second angled planes at said upper end of said main body form an angle of approximately 5-25 degrees.

21. The spacer as claimed in claim 20, wherein said first and second angled planes at said upper end of said main body form an angle of approximately 10-20 degrees. 5
22. The spacer as claimed in claim 1, wherein said endplates are oriented for pivoting in a sagittal plane of a spine. 10
23. The spacer as claimed in claim 1, wherein said main body has a cross-sectional diameter of approximately 10-30 mm. 15
24. The spacer as claimed in claim 1, wherein said endplates have a diameter of approximately 30-50 mm. 20
25. The spacer as claimed in claim 24, wherein said endplates have a diameter of approximately 35-40 mm. 25
26. A vertebral body spacer comprising:
 - a main body including an upper end and a lower end, said upper end having a first concave socket and an upper edge surrounding said first concave socket defining first and second planes angled relative to one another, said lower end having a second concave socket and a lower edge surrounding said second concave socket defining first and second planes angled relative to one another; 30
 - a first endplate pivotally secured to said upper end of said main body for pivoting between said first and second planes of said upper edge, said first endplate including an underside having a convex projection adapted to engage said first concave socket; 35
 - a second endplate pivotally secured to said lower end of said main body for pivoting between said first and second planes of said lower edge, said second endplate including an underside having a convex projection adapted to engage said second concave socket. 40
27. The spacer as claimed in claim 26, wherein said convex projections form ball and socket joints with the respective said first and second concave sockets. 45
28. The spacer as claimed in claim 26, wherein said upper edge includes at least one retainer clip projecting therefrom for pivotally securing said first endplate to said main body. 50

29. The spacer as claimed in claim 28, wherein said first endplate includes at least one retainer clip aperture extending therethrough, and wherein said at least one retainer clip is passable therethrough. 55
30. The spacer as claimed in claim 28, wherein said first endplate includes a series of apertures extending therethrough for receiving bone growth material and facilitating spinal fusion.
31. The spacer as claimed in claim 26, wherein said lower edge includes at least one retainer clip projecting therefrom for pivotally securing said second endplate to said main body.
32. The spacer as claimed in claim 31, wherein said second endplate includes at least one retainer clip aperture extending therethrough, and wherein said at least one retainer clip is passable therethrough.
33. The spacer as claimed in claim 32, wherein said second endplate includes a series of apertures extending therethrough for receiving bone growth material and facilitating spinal fusion.

FIG. 1

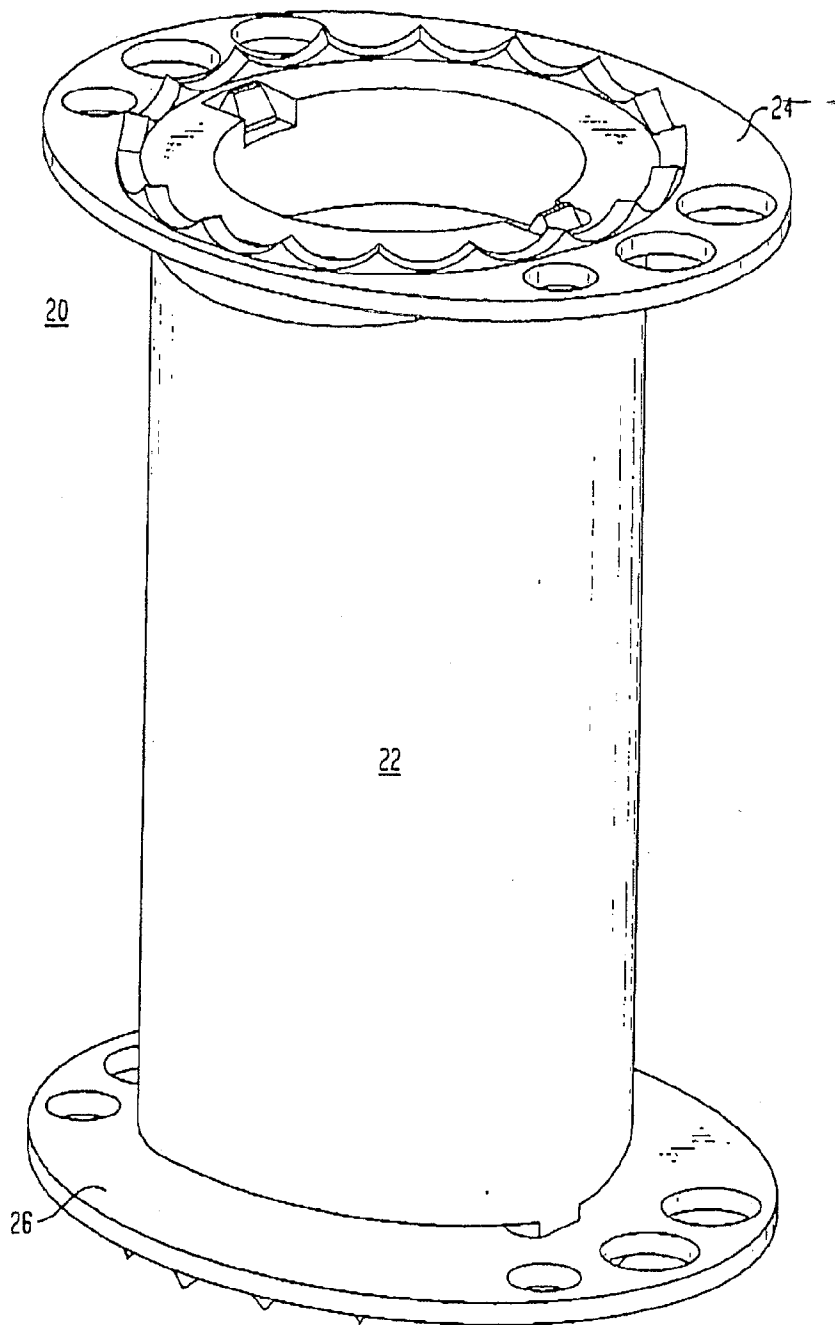


FIG. 2

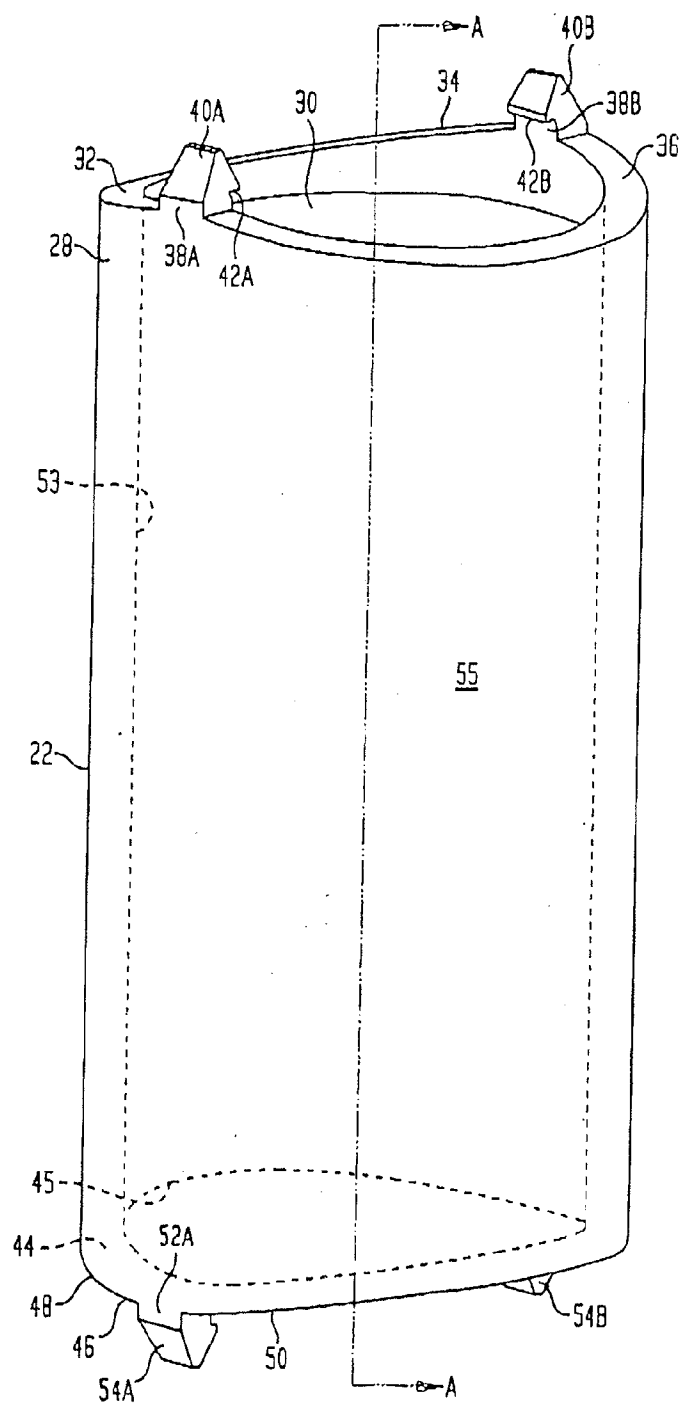


FIG. 3

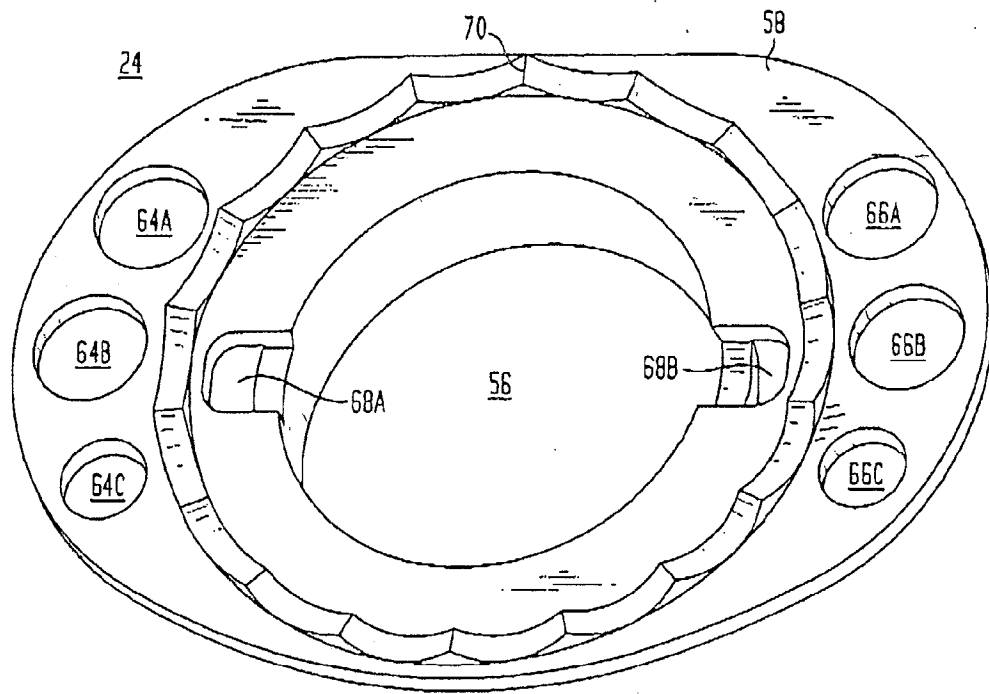


FIG. 4

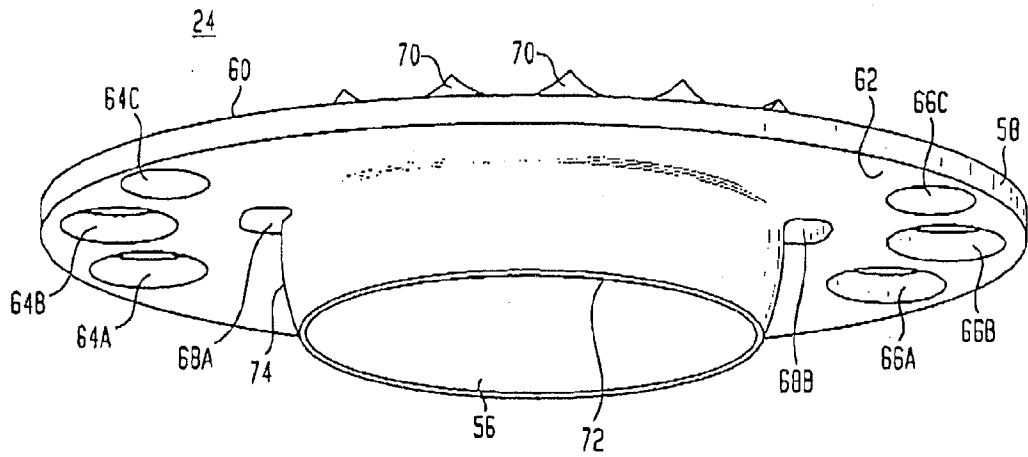


FIG. 5

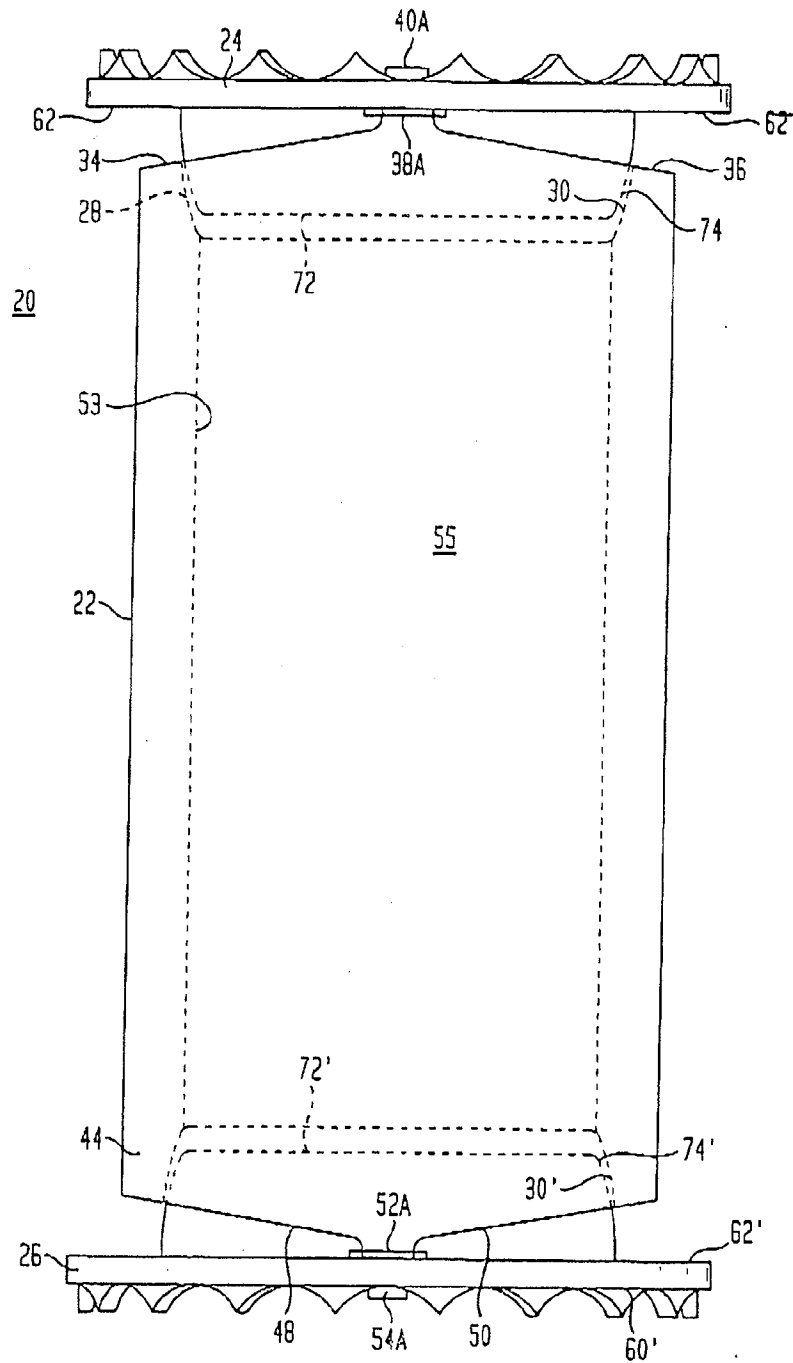


FIG. 6

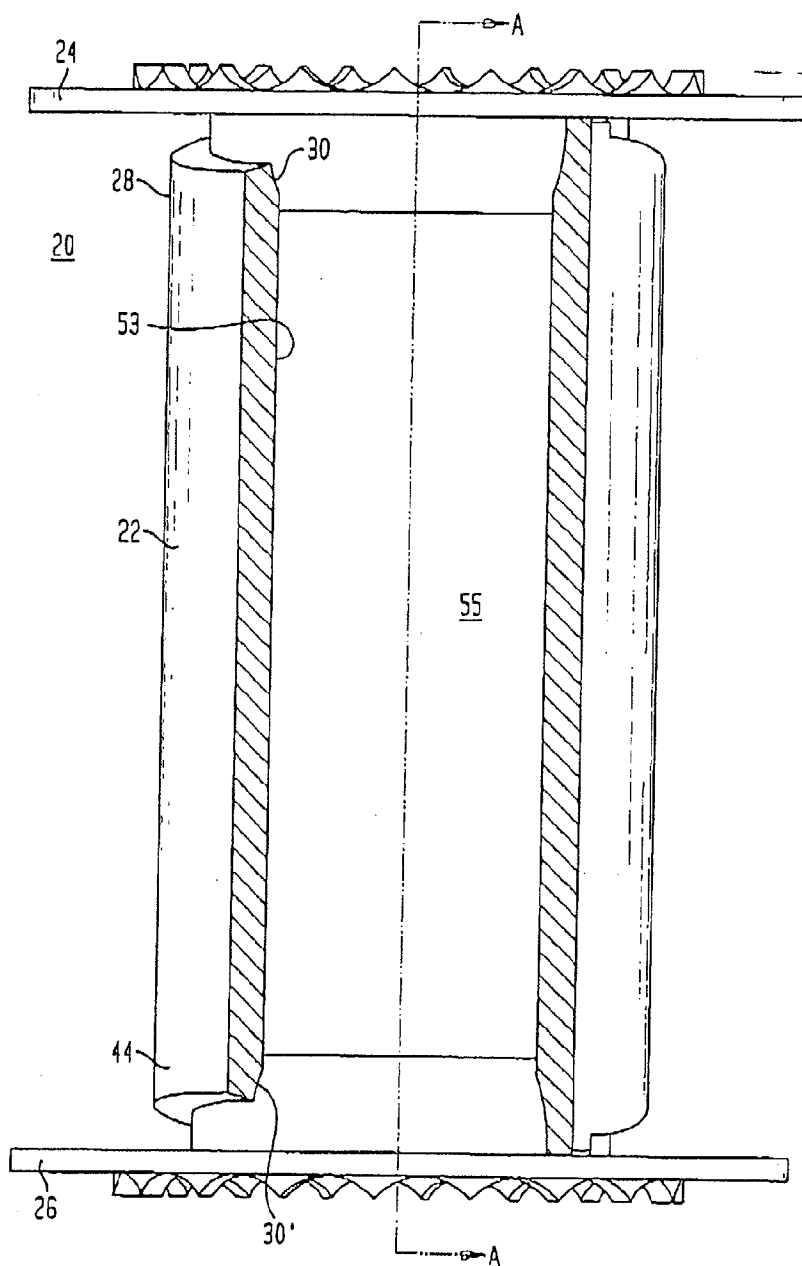


FIG. 7A

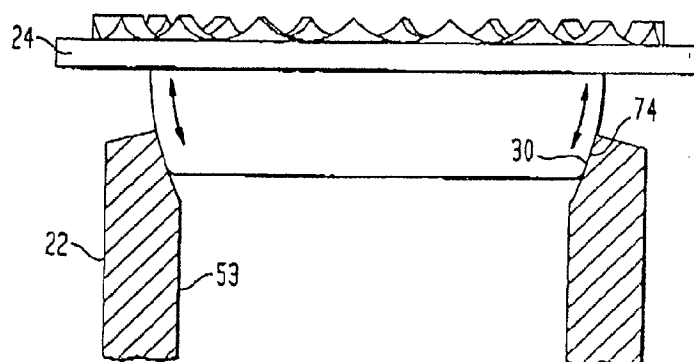


FIG. 7B

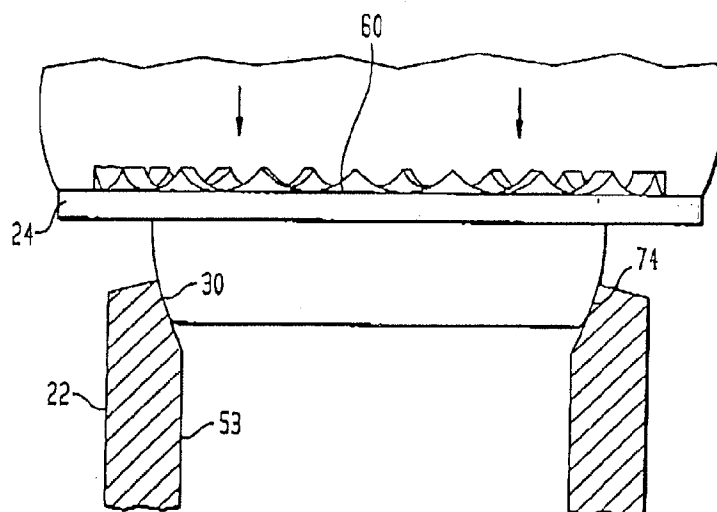


FIG. 8A

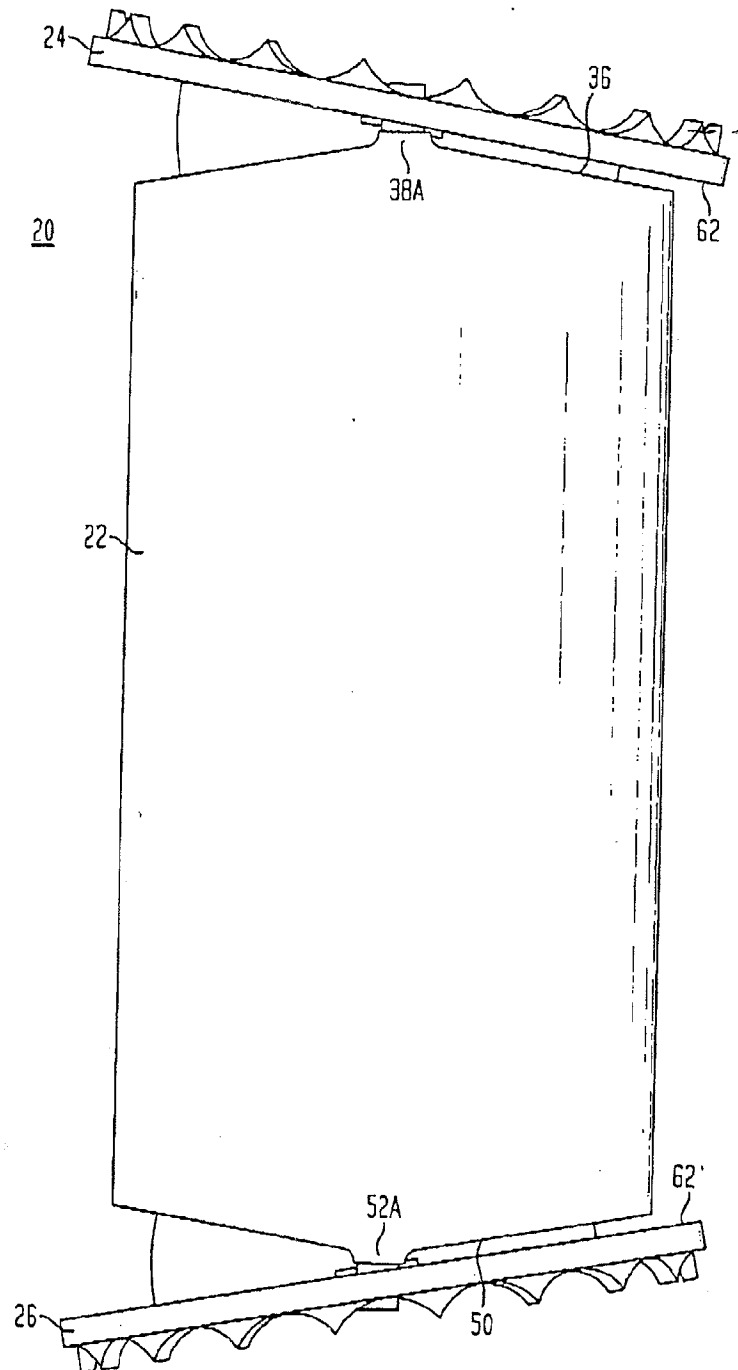


FIG. 8B

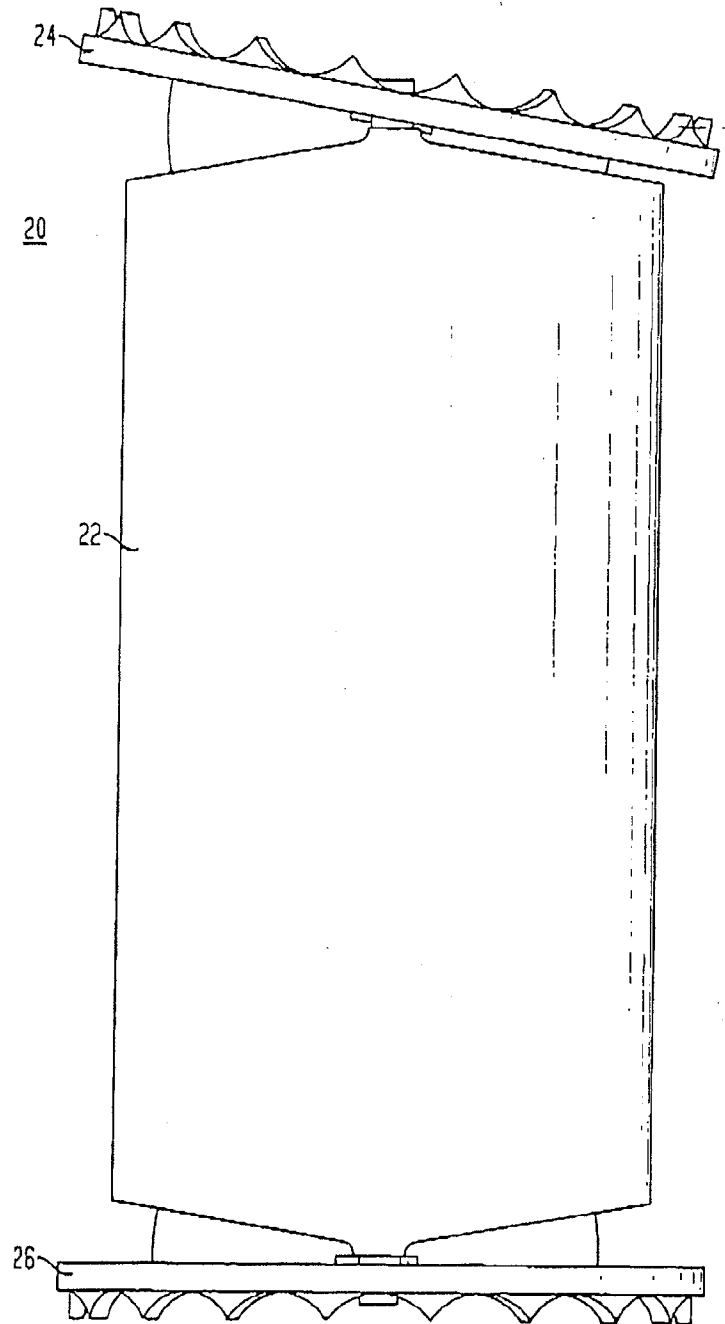
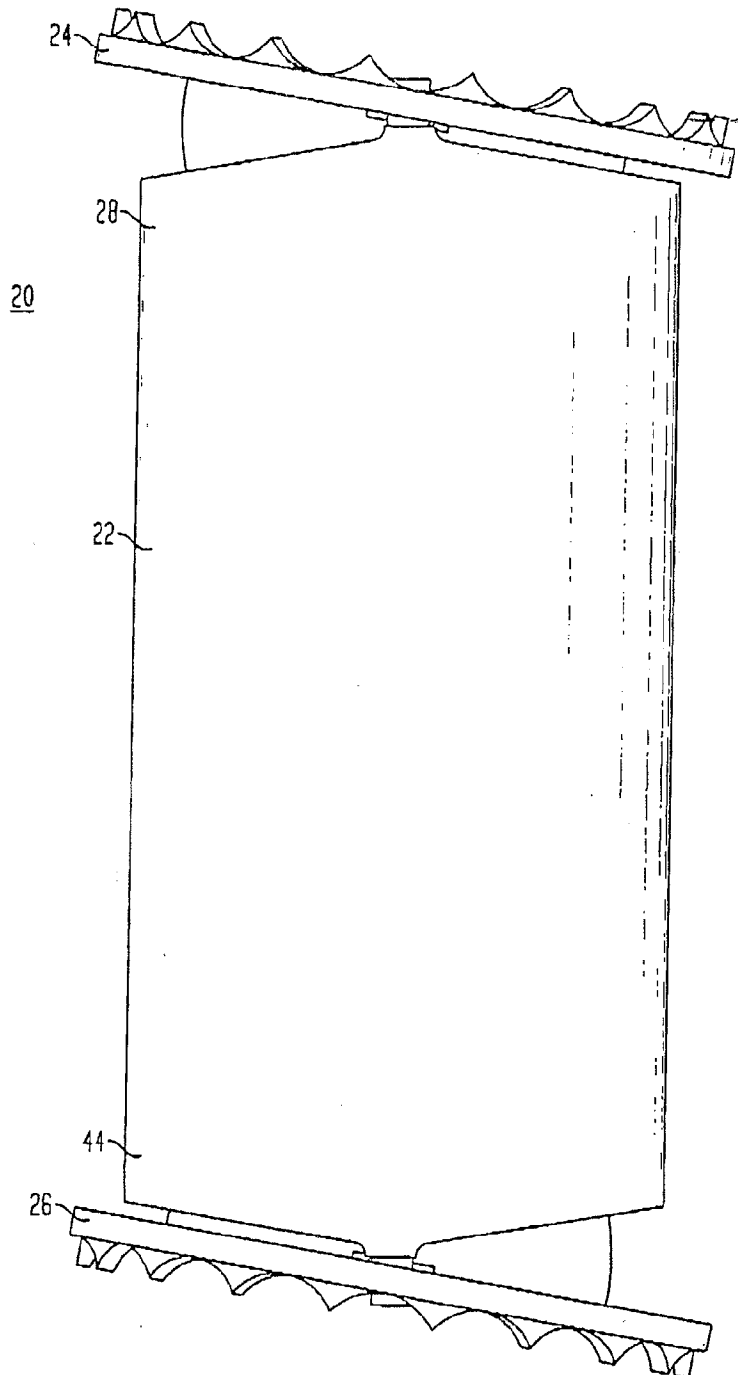


FIG. 8C





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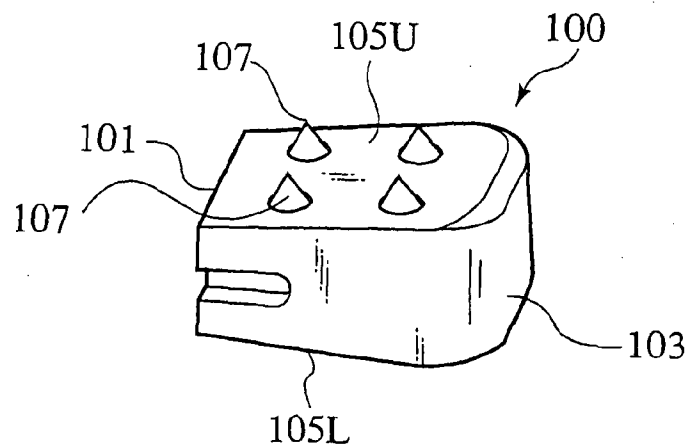
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(54) **Intervertebral spacer**

(57) The upper and lower surfaces 5 and 7 of an intervertebral spacer 1 inserted between the vertebrae of a spine are formed in the shape of a curved surfaces 21A and 21B each having a top portion at the middle portion in the back and forth direction. The above-men-

tioned upper and lower surfaces 5 and 7 are provided with a plurality of claw portions 17 for preventing withdrawal. Further, the intervertebral spacer 1 is formed in such a way that a tip portion in the direction of insertion is tapered.

FIG.1A



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Description

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is based upon and claims the benefit of priority from the prior Japanese Patent Applications No. P2002-239086 filed on August 20, 2002; the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The invention relates to an intervertebral spacer that is inserted between vertebrae, after an intervertebral disk is previously removed, to thereby be put into contact in almost whole area with an end plate of the vertebra.

2. Description of the Related Art

[0003] There have been known intervertebral spacers inserted between the vertebrae the intervertebral disk of which is removed. Japanese Patent Application Laid-Open No. 2002-95685 (hereinafter referred to as a related art) shown in Figs. 1A to 1C discloses one example of conventional intervertebral spacers.

[0004] As shown in Fig. 1A, a thickness of a rear side 101 of an intervertebral spacers 100 is larger than that of a front side 103 of an intervertebral spacers 100. An upper surface 105U and a lower surface 105L of the intervertebral spacers 100 are slanting each other, and are flat planes. Each of the slanting upper and lower surfaces 105U and 105L has a plurality of conical protruding portions 107. The intervertebral spacer 100, as shown in Fig. 1B and 1C, is inserted between vertebrae 109A and 109B from a posterior side after an intervertebral disk is removed.

[0005] In the related art, the protruding portions 107 enhance an effect of preventing the intervertebral spacer 100 from coming off. However, the intervertebral spacer 100 has the following problems: since the front side 103 of the spacer 100 is thicker than that of the rear side 101, when the intervertebral spacer 100 is inserted between the upper and lower vertebrae 109A and 109B, it is hard to insert; further, since the upper and lower surfaces 105U and 105L are slanting each other, the end plates of the upper and lower vertebrae 109A and 109B are not put into whole surface contact with the upper and lower surfaces 105U and 105L. Hence, the contact area between them becomes small, so that the intervertebral spacer 100 can not sufficiently fix the vertebrae 109a and 109B.

SUMMARY OF THE INVENTION

[0006] This invention has been made to solve the

problems. According to the aspect of the invention, there is provided an intervertebral spacer that is inserted between the vertebrae of a spine and includes a main body and withdrawal prevention means formed on the upper and lower surfaces, and formed in asymmetrically in a sectional side view, wherein the withdrawal prevention means comprises a plurality of linear claw portions formed from one side surface of the main body to the other side surface.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007]

Fig. 1A is a perspective view of a conventional intervertebral spacer.

Fig. 1B is a side view of the conventional intervertebral spacer inserted between the vertebrae.

Fig. 1C is a front view of the conventional intervertebral spacer inserted between the vertebrae.

Fig. 2A is a perspective view of an intervertebral spacer according to a first embodiment of the present invention.

Fig. 2B is a sectional side view of the intervertebral spacer according to the first embodiment of the present invention.

Fig. 2C is a rear view of the intervertebral spacer according to the first embodiment of the present invention.

Fig. 3A is a perspective view of an intervertebral spacer according to a second embodiment of the present invention.

Fig. 3B is a sectional side view of the intervertebral spacer according to the second embodiment of the present invention.

Fig. 3C is a rear view of the intervertebral spacer according to the second embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

First embodiment

[0008] As shown in Figs. 2A to 2C, an intervertebral spacer 1 according to a first embodiment of the present invention is inserted between the vertebrae (not shown) after an intervertebral disk is removed.

[0009] A front end portion 9 of the main body 3 is formed in a tapered curved surface, for example, a spherical surfaces such that its forefront side gradually becomes small. In a rear end portion 11 of the main body 3, a tool engagement portion 15 is provided. A tool such as a pair of forceps is engaged with the tool engagement portion 15 when the intervertebral spacer 1 is inserted between the vertebrae.

[0010] On an upper surface 5 and a lower surface 7 of the main body 3, from one side of the intervertebral spacer 1 to the other side, claw portions 17 for prevent-

ing withdrawal are formed. Each claw portion 17 is formed in the shape of a triangle in cross section in the direction of insertion, in which a slanting angle α in the direction of insertion is small and a slanting angle β in the direction of withdrawal is larger than the slanting angle α so that the intervertebral spacer 1 can be easily inserted when it is inserted between the vertebrae and is hard to remove when it is removed.

[0011] In the main body 3, the claw portions 17 on the upper and lower surfaces 5 and 7 are arranged along imaginary slanting planes 19A and 19B slanting in such a way that the distance between the upper surface 5 and the lower surface 7 becomes narrower in the rear side 11 than in the front side 9. The ridges (vertexes) of the claw portions 17 are arranged along a curved surface 21A (or 21B), and the top portion of the claw portions 17 is positioned at the middle portion in the cross direction of the main body 3. The front portion 9 formed in the tapered curved surface protrudes from near the portions where the slanting surfaces 19A and 19B cross the curved surfaces 21A and 21B at the front end side. The rear end surface is positioned near the portions where the slanting surfaces 19A and 19B cross the curved surfaces 21A and 21B at the rear end side.

[0012] As is the case with the related art, the front end portion 9 of the main body 3 is inserted between the vertebrae from the rear side of the vertebrae after the intervertebral disk is removed. At this time, since the front end portion 9 is formed in the tapered curved surface and the slanting angle α of the claw portions 17 is small, the main body 3 can be easily inserted between the vertebrae.

[0013] After the main body 3 is inserted, the vertebrae sandwiching the main body 3 are fixed to each other by implants or the like (not shown) so that they do not move. At this time, the plurality of upper and lower claw portions 17 on the main body 3 bite into the upper and lower vertebrae to produce an effect of preventing withdrawal. And the ridges of the plurality of claw portions 17 are put into contact with almost all the surfaces of end plates of the upper and lower vertebrae because the ridges are formed along the arc-shaped curved surfaces 21A and 21B the top portions of which are positioned at the middle portion in the cross direction of the main body 3. For this reason, the intervertebral spacer 1 is sufficiently fixed between the vertebrae to thereby solve the problems of the related art.

[0014] Figs. 3A to 3C show a second embodiment of the present invention. The constituent parts performing the same functions as the constituent parts shown in the first embodiment are denoted by the same reference symbols and their descriptions will be omitted.

[0015] This second embodiment is different from the first embodiment in the point that the imaginary slanting planes 19A and 19B are formed in planes 23A and 23B parallel to each other and is the same in the other points of construction as the first embodiment.

[0016] This second embodiment can produce the

same effect as the first embodiment.

Claims

1. An intervertebral spacer inserted between vertebrae of a spine comprising:

a main body defined by a pair of upper and lower surfaces and a pair of side surfaces connected to the upper and lower surfaces; and withdrawal prevention means formed on the upper and lower surfaces of the main body, and formed in asymmetrically in a sectional side view, wherein

the withdrawal prevention means comprises a plurality of linear claw portions formed from one side surface of the main body to the other side surface.

2. The intervertebral spacer according to claim 1, wherein each of the upper and lower surfaces of the main body is formed in a curved surface having a top portion at a middle portion in a cross direction.
3. The intervertebral spacer according to claim 1, wherein each claw portion being formed in an asymmetric triangle shape, in a sectional side view, defined by a first surface in the direction in which the intervertebral spacer is inserted, a second surface connected to a rear side of the first surface and the upper surface or the lower surface of the main body.
4. The intervertebral spacer according to claim 2, wherein the main body is formed in a shape of a curved surface on an insertion side such that it is tapered on the insertion side as compared with a rear side.
5. The intervertebral spacer according to claim 3, wherein an angle formed by the first surface of the claw piece and the upper or the lower surface of the main body is larger than an angle formed by the second surface and the upper surface or the lower surface of the main body.

FIG.1A

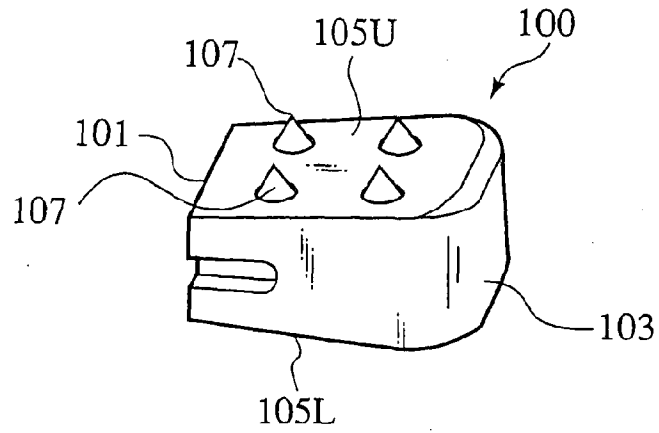


FIG.1B

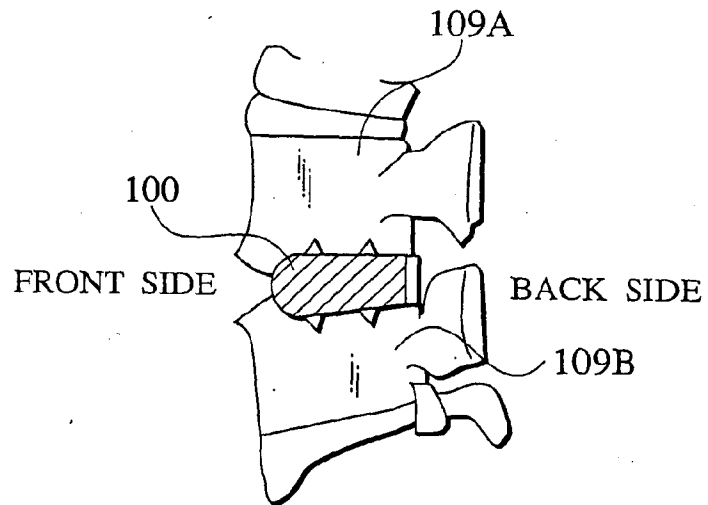


FIG.1C

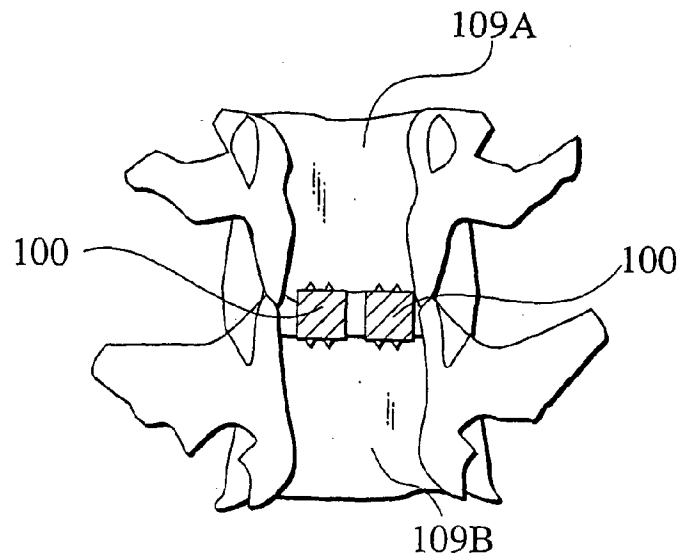


FIG.2A

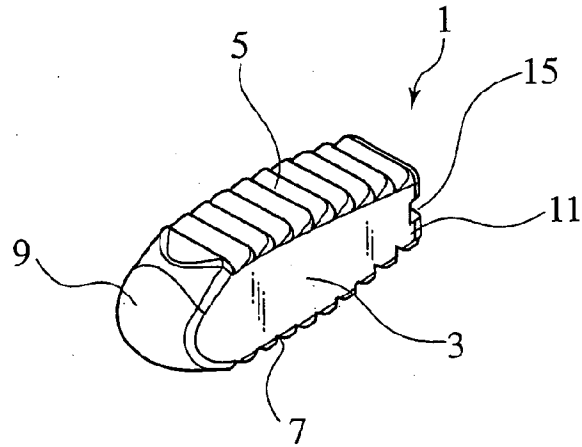


FIG.2B

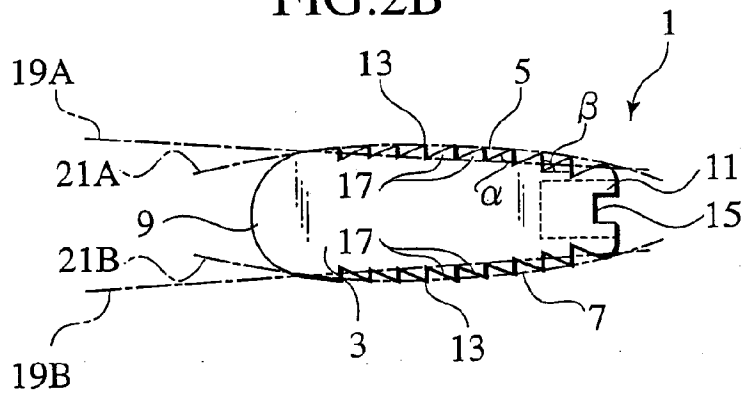


FIG.2C

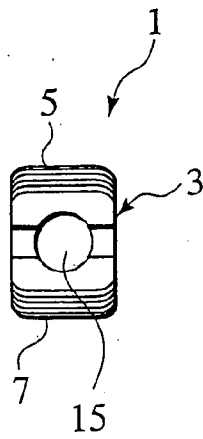


FIG.3A

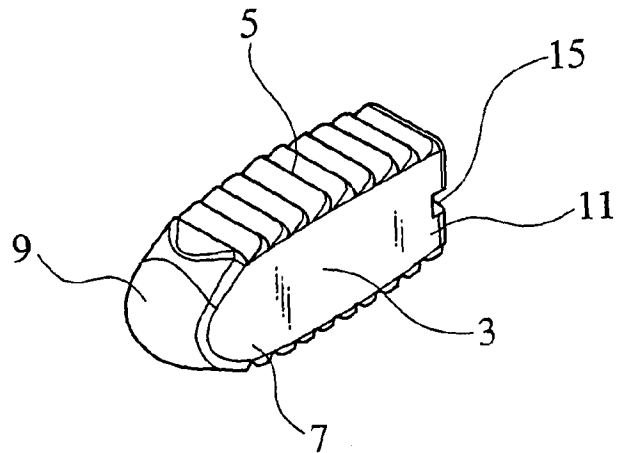


FIG.3B

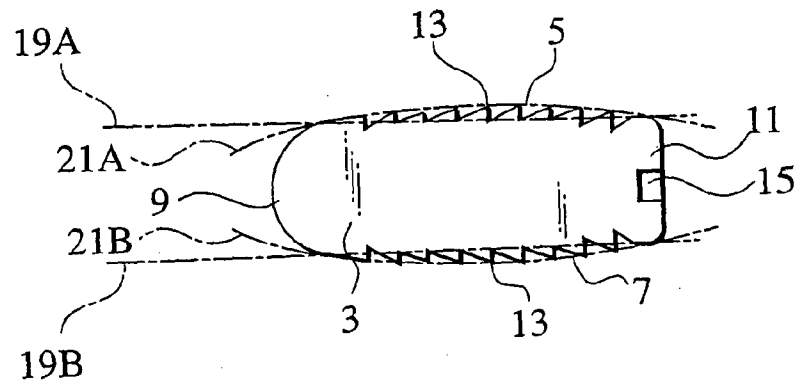
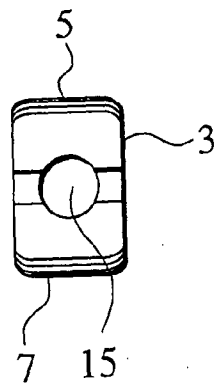


FIG.3C





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 03 01 8956

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P,X	US 6 500 206 B1 (BRYAN DONALD W) 31 December 2002 (2002-12-31) * figures 1A-2 * * column 6, line 62 - column 7, line 13 * -----	1,3,5	<div>TECHNICAL FIELDS SEARCHED (Int.Cl.7)</div> <div>A61F</div>
The present search report has been drawn up for all claims			
Place of search BERLIN		Date of completion of the search 27 November 2003	Examiner Stach, R
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

EPO FORM 1503 03/82 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 03 01 8956

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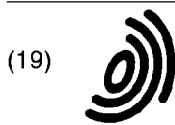
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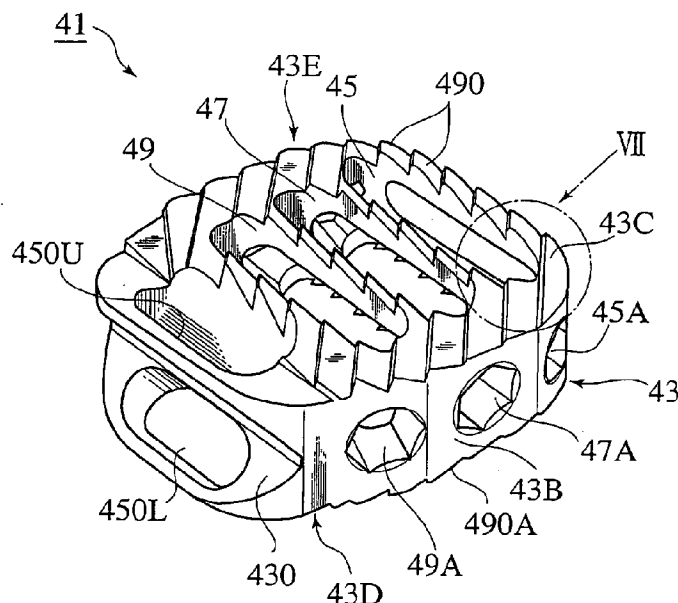
(54) Intervertebral cage

(57) An intervertebral cage 41 of the present invention is comprised of a main body 43 defined by an upper surface 43 E, a lower surface 43 D, a pair of side surfaces 43A, 43B; and withdrawal prevention means

formed on the upper and/or the lower surfaces of the main body 43 and asymmetrically in a sectional side view.

The withdrawal prevention means regulates an insertion direction of the intervertebral cage 41.

FIG.3



Description

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is based upon and claims the benefit of priority from the prior Japanese Patent Applications No. P2002-239095 filed on August 20, 2002; the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The invention relates to an intervertebral cage that can be inserted between upper and lower vertebrae in longitudinal and slating directions after an intervertebral disk is removed.

2. Description of the Related Art

[0003] There have been known intervertebral cages inserted between the vertebrae the intervertebral disk of which is removed.

[0004] Figs. 1 and 2 show an intervertebral cage of a related art of this invention (Japanese Unexamined Patent Publication No. 9-503416). In the related art, an intervertebral cage 50 is comprised of a pair of left and right semicircular lateral spacers 51A, 51B; front and rear central spacers 53A, 53B are integrally fixed to each other by left and right fixing screws 55. This intervertebral cage 50 is inserted between upper and lower vertebrae 59U, 59L after an intervertebral disk is removed. The central spacers 53A, 53B and lateral spacers 51A, 51B define a cavity 70.

[0005] The related art has a problem that 1) since the intervertebral cage 50 is comprised of a large number of components and has a complex structure, and 2) does not have protrusions for preventing itself from coming off, it can not sufficiently be fixed between the vertebrae after it is inserted between the vertebrae.

[0006] Further, in the related art, it is premised that the intervertebral cage 50 is inserted between the upper and lower vertebrae from an anterior side but is not inserted from longitudinal and slanting anterior sides. Thus, an improved intervertebral cage has been desired.

SUMMARY OF THE INVENTION

[0007] This invention has been made to solve the above-mentioned problems. According to an aspect of the invention, there is provided an intervertebral cage inserted between vertebrae of a spine comprising: a main body defined by a pair of upper and lower surfaces and a pair of side surfaces connected thereto; and withdrawal prevention means formed on the upper and/or the lower surfaces of the main body and asymmetrically

in a sectional side view, wherein the withdrawal prevention means regulates an insertion direction of the intervertebral cage.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008]

Fig. 1 is a perspective view of a conventional intervertebral cage.

Fig. 2 is a side view of a conventional intervertebral cage inserted between the intervertebrae.

Fig. 3 is a perspective view of an intervertebral cage of the present invention.

Fig. 4A is a plan (top plan) view of the intervertebral cage of the present invention.

Fig. 4B is a plan (bottom) view of the intervertebral cage of the present invention.

Fig. 5 is a sectional side view of the intervertebral cage of the present invention.

Fig. 6 is a rear view of the intervertebral cage of the present invention.

Fig. 7 is a partially enlarged view of Fig. 3.

Figs. 8A and 8B show an insertion direction of the intervertebral cage to vertebrae.

DETAILED DESCRIPTION OF THE INVENTION

[0009] An embodiment according to the present invention will be described with reference to Figs. 3 to 8B.

[0010] An intervertebral cage 41 includes a hollow main body 43 and withdrawal prevention means integrally formed on the upper and lower surfaces of the main body 43.

[0011] As shown in Figs. 4A and 4B, the main body 43 is roughly formed in a deformed hexagon, and each corner is formed in a circular arc. Further, as shown in Fig. 5, the thickness H2 of the rear end side of the main body 43 is larger than the thickness H1 of the front end side (tip end side) of the main body 43.

[0012] A front hole 45, a center hole 47 and a rear hole 49 each having a length L1 are respectively formed in the front side (43F side), the central portion and the rear side portion of the main body 43 from an upper surface 43E of the main body 43 to a lower surface 43D in the longitudinal direction with respect to the direction in which the intervertebral cage 41 is inserted. Further, a hole 410 (see Fig. 5) that is formed in the cross direction and made nearly equal in length in the longitudinal direction to the respective holes 45, 47 and 49 (that is, the length L1 shown in Fig. 4A is nearly equal to the length L2 shown in Fig. 5) is formed in the main body 43 from a front surface 43F to the rear hole 49.

[0013] Since the front hole 45, the center hole 47, the rear hole 49 and the hole 410 are formed in the main body 43, the main body 43 is formed in a hollow body. Transverse through holes 45A, 47A and 49A are respectively formed at positions corresponding to the front hole

45, the center hole 47 and the rear hole 49 in the both side surfaces 43A and 43B of the main body 43 (see Fig. 3).

[0014] Further, a groove 430 formed in the V-shaped in a sectional side view is made in the rear end surface of the main body 43. Upper and lower screw through holes 450U and 450L made through the upper surface 43E and lower surface 43D are formed in the groove 430 in the slanting and vertical direction. Each of these screw through holes 450U and 450L is formed in a hole elongated in the longitudinal direction.

[0015] The withdrawal prevention means according to the present invention will be described with reference to Fig. 7.

[0016] In a corner 43C, a plurality of notches (claw portions 490) are formed in parallel to a line 470 perpendicular to a bisector of a vertical angle formed by the side surface 43B and the front surface 43F. Each of the plurality of claw portions 490 is nearly formed in a wedge shape, and one surface 490A of the claw portions 490 is set at a length shorter than that of the other surface 490B connected thereto. The intervals between the respective claw portions 490 can be set at appropriate values. Further, a plurality of claw portions 490 are formed in the same way also on the surface (lower surface 43D shown in Fig. 4B) opposite to the surface (upper surface 43E) shown in Fig. 7 of the main body 43. At this time, in the end portion on the side opposite to the corner 43C of the upper surface 43E, claw portions 490A are formed in parallel to a line 470A perpendicular to a bisector of a vertical angle formed by a side surface 43A and the front surface 43F. As a result, the claw portions 490 and 490A formed on the upper surface 43E and the lower surface 43D are provided symmetrically with respect to a horizontal cut plane of the upper surface 43E and the lower surface 43D.

[0017] Since the claw portions 490 and 490A are formed at a predetermined slanting angle with respect to the side surfaces 43A and 43B of the intervertebral cage 41, the insertion direction of the intervertebral cage 41 is regulated. That is, the insertion direction is regulated in a direction B vertical to the cutting lines 470 and 470A (Figs. 4A, 4B). Further, the intervertebral cage 41 can be inserted either in a left direction or in a right direction with respect to the vertebrae, depending on which surface of the upper and lower surfaces is faced upward.

[0018] When the intervertebral cage 41 is inserted between the upper and lower vertebrae after the intervertebral disk is removed, the main body 43 is held by engaging a tool such as a pair of forceps with the transverse holes 45A, 47A and 49A and is inserted between the vertebrae BV from the left and front side of a spine V such that, as shown in Fig. 8A, the one corner 43C of the main body 43 goes ahead. By turning the intervertebral cage 41 upside down, as shown in Fig. 8B, the main body 43 can be inserted between the vertebrae BV from the right and front side.

[0019] Thus, even in a case where, for example, an organ is positioned in front of the spine, the main body 43 can be inserted between the vertebrae of the spine while avoiding the organ. At this time, in the main body 43, the rear end side is formed more thinly than the front end side, so that the main body 43 can be easily inserted between the vertebrae.

[0020] Further, after the main body 43 is inserted between the vertebrae, the cutting lines 470 and 470A of the plurality of claw portions 490 and 490A for preventing withdrawal, formed in the upper and lower surfaces 43D and 43E, bite into the end plates of the upper and lower vertebrae to thereby prevent the main body 43 from coming off between the vertebrae. Still further, by screwing implant screws S from the V-shaped groove 430 formed on the rear end surface of the main body 43 through the screw through holes 450U and 450L into the upper and lower vertebrae sandwiching the intervertebral cage 41, the main body 43 can be fixed between the upper and lower vertebrae with reliability. At this time, since the screw through holes 450U and 450L are elongated in lateral direction, the position into which the implant screws are screwed can be shifted in the longitudinal direction in response to the state of the vertebrae.

[0021] As described above, after the main body 43 is fixed between the upper and lower vertebrae, bone grows and gets into the front vertical hole 45, the center vertical hole 47 and the rear vertical hole 49, which are formed in the upper and lower surfaces of the main body 43 to thereby promote bone fusion. Then, it is possible to judge the bone fusion by passing X-rays through the transverse through holes 45A, 47A and 49A formed in correspondence to the respective vertical holes 45, 47 and 49 and taking an X-ray picture.

Claims

1. An intervertebral cage inserted between vertebrae of a spine comprising:

a main body defined by a pair of upper and lower surfaces and a pair of side surfaces connected thereto; and
withdrawal prevention means formed on the upper and/or the lower surfaces of the main body and asymmetrically in a sectional side view,

wherein the withdrawal prevention means regulates an insertion direction of the intervertebral cage.

2. The intervertebral cage according to claim 1, wherein the withdrawal prevention means are formed along with a plurality of parallel cutting lines slanting at a predetermined angle with respect to

one of the side surfaces of the main body.

3. The intervertebral cage according to claim 1, wherein the main body is formed in a hollow body and is made thicker on a front side in the direction of insertion than on a rear side, 5
- wherein the withdrawal prevention means comprises a plurality of claw portions whose cutting lines are formed in a direction nearly perpendicular to a bisector nearly bisecting an angle of one corner of a front portion in the direction of insertion of the main body, 10
- and wherein a screw through hole passing through surfaces which form a V-shaped groove in a sectional side view in a rear end surface of the main body and are opposed to each other is formed. 15
4. The intervertebral cage according to claim 3, wherein the screw through hole is an elongated hole made in a direction perpendicular to a longitudinal direction of the intervertebral cage. 20
5. The intervertebral cage according to claim 2, wherein the direction of insertion is regulated in a direction perpendicular to the cutting lines. 25
6. The intervertebral cage according to claim 3, wherein the main body has a vertical through hole passing through the upper and lower surfaces, a transverse through hole passing through the side surfaces from one side to the other side, and a hole formed from a front end surface in a direction of insertion of the main body to a rear end surface opposite to the front end surface. 30

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FIG.1

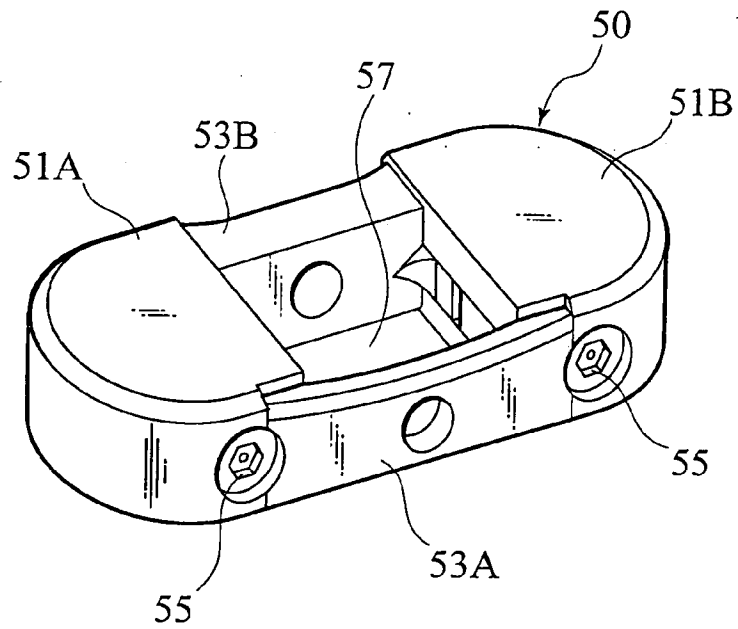


FIG.2

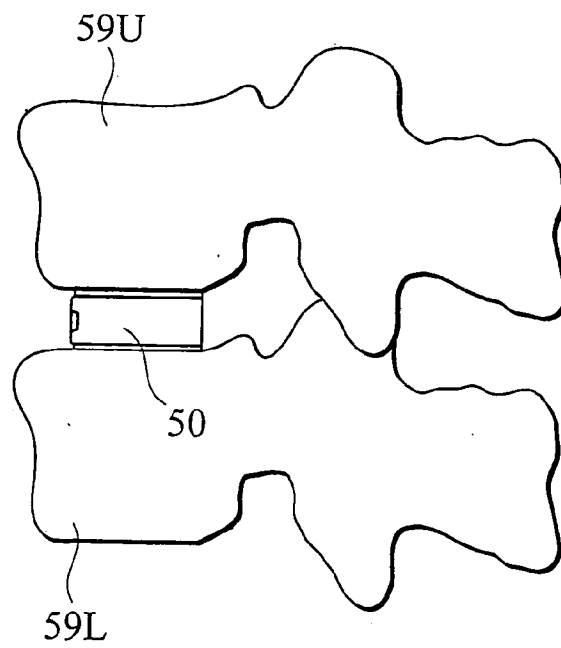


FIG.3

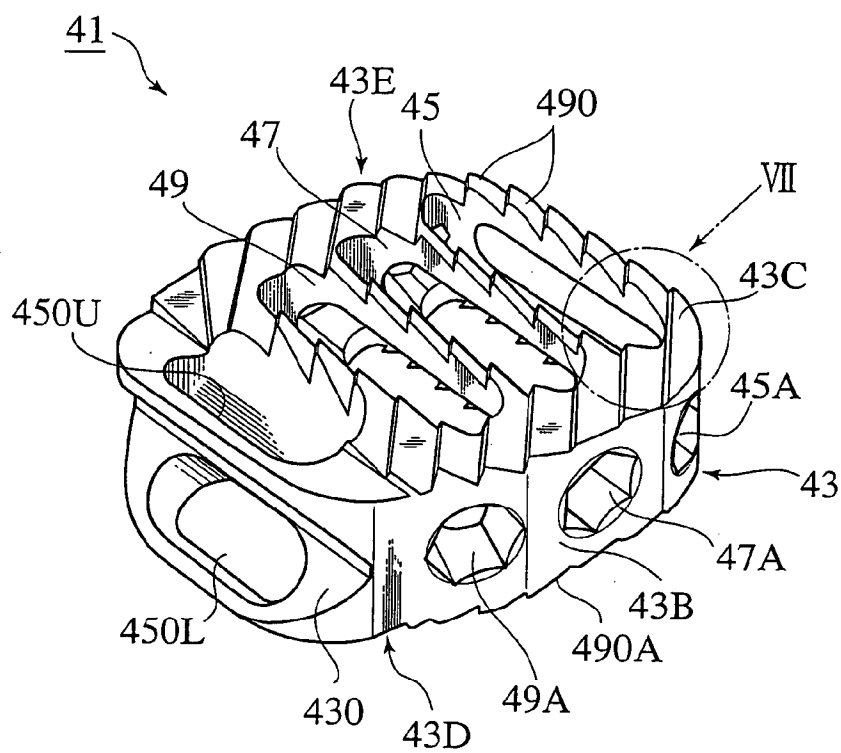


FIG.4A

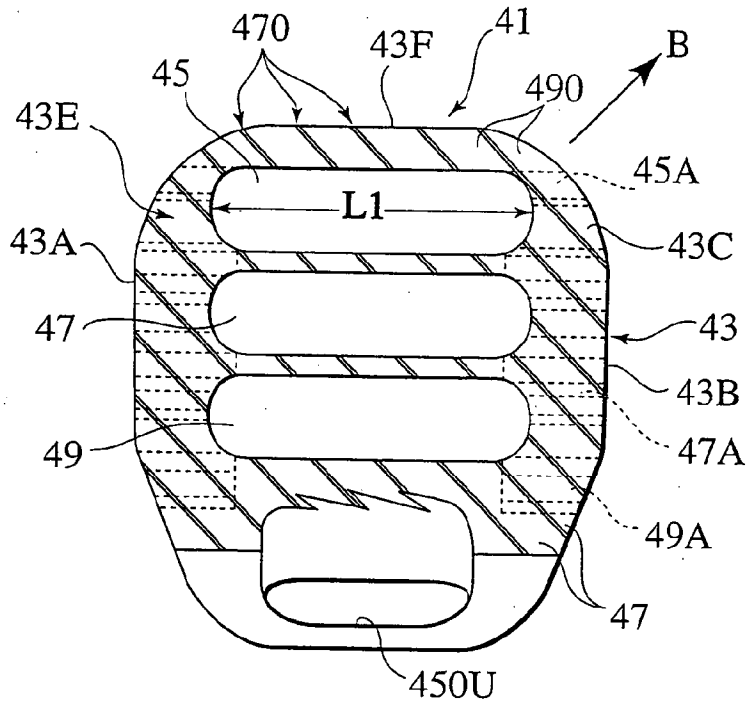


FIG.4B

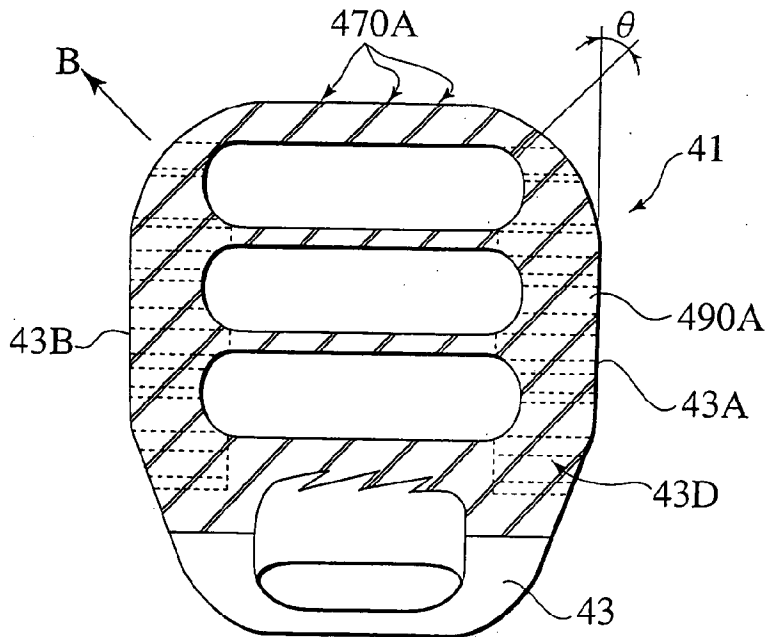


FIG.5

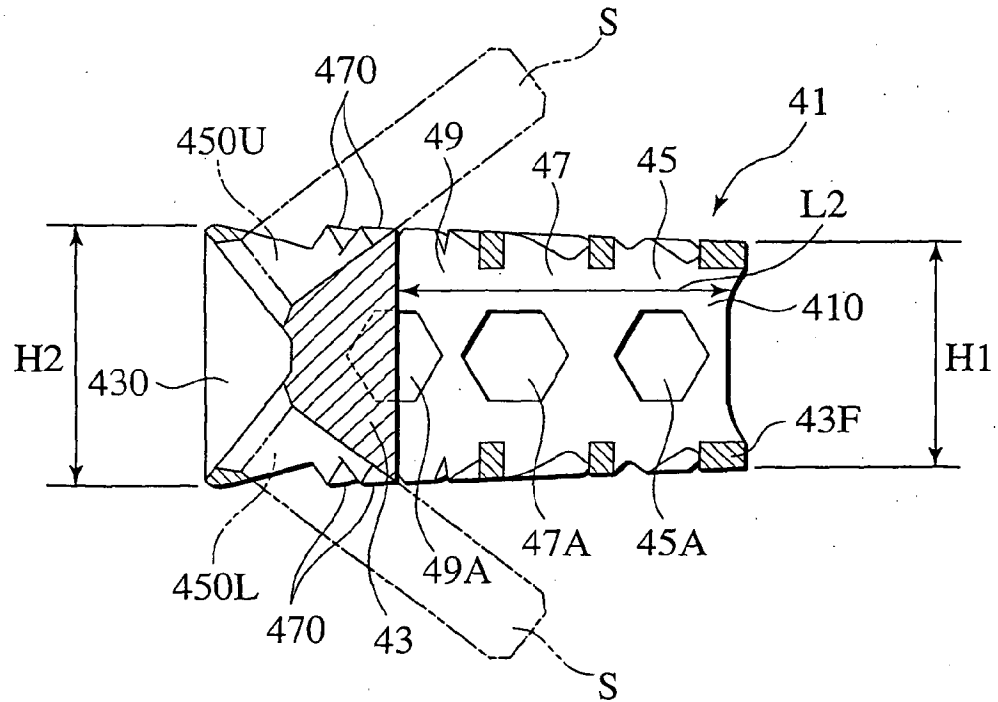


FIG.6

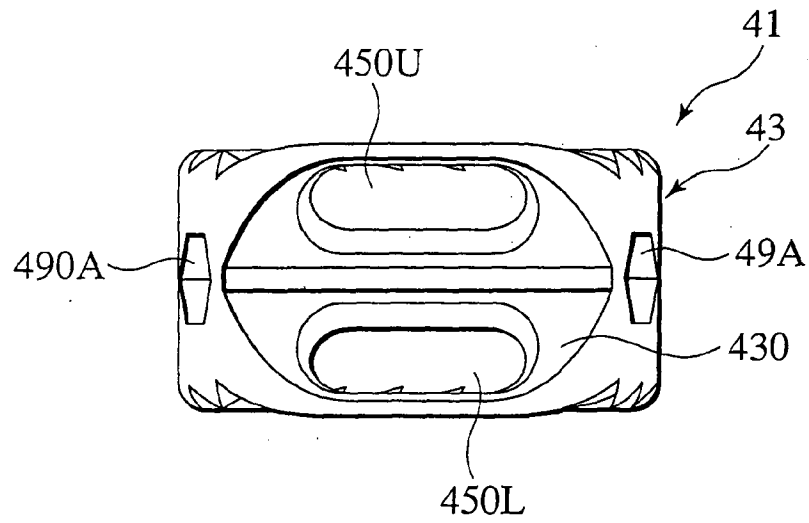


FIG.7

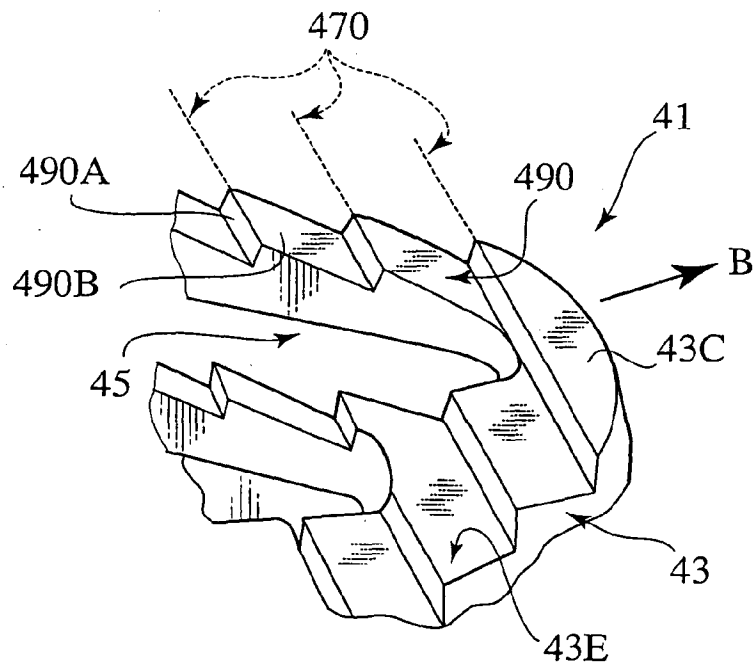


FIG.8A

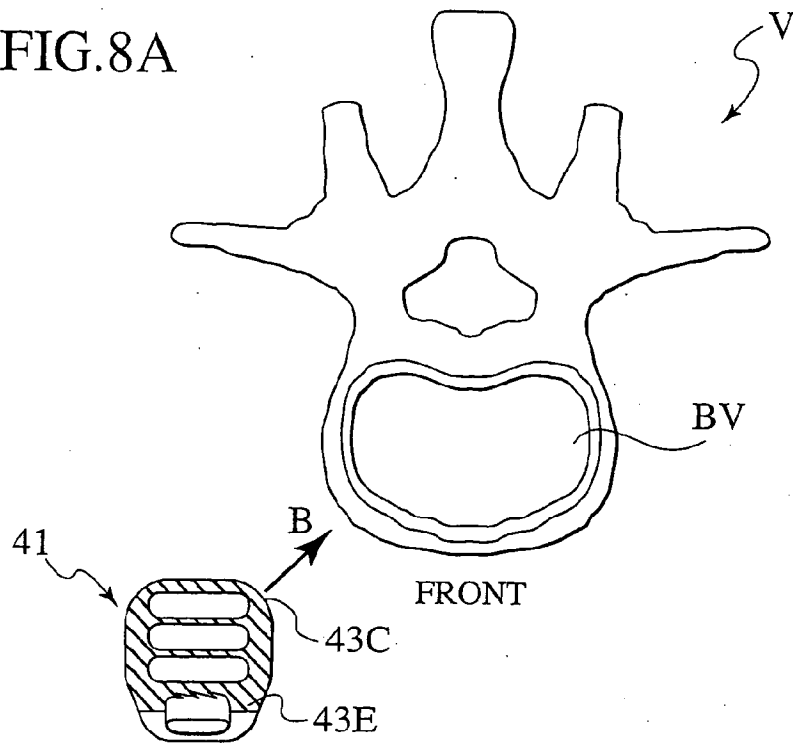
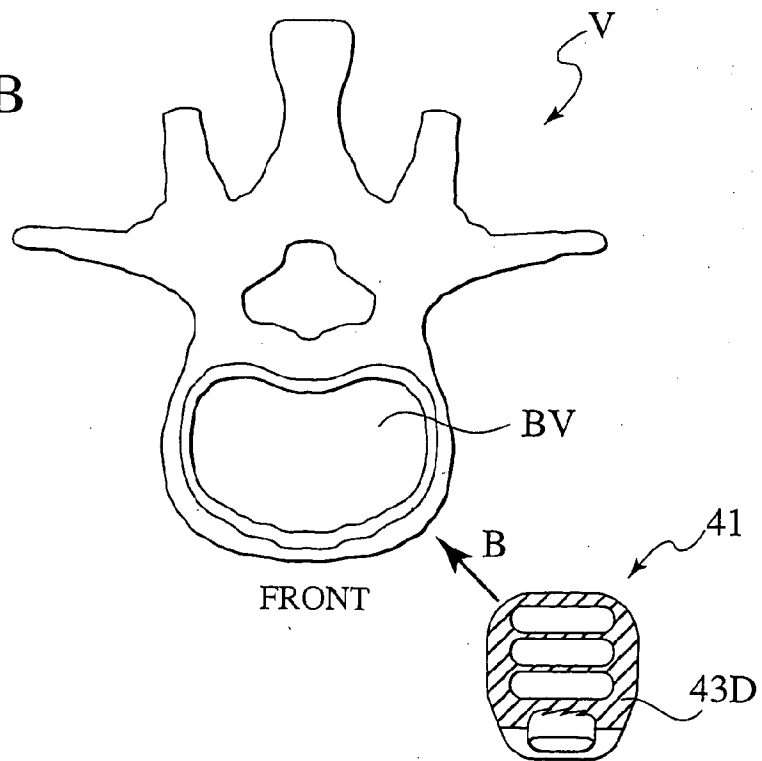


FIG.8B





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Y	---	3	
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A	---	2,3,5	
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			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61F
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<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03/02 (P04G01)

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(11) **EP 1 398 008 A1**

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(54) **Platzhalter für Wirbelkörper oder Bandscheiben**

(57) Es wird ein Platzhalter für Wirbelkörper oder Bandscheiben bereitgestellt, der einen rohrförmigen Abschnitt (100) und Zacken (103, 104) an den jeweiligen Enden des Platzhalters aufweist. An zumindest ei-

nem Ende des rohrförmigen Abschnittes ist ein Element (101) vorgesehen, welches eine Deckplatte (102) aufweist, die um einen Winkel zur Längsachse des rohrförmigen Abschnittes kippbar ist.

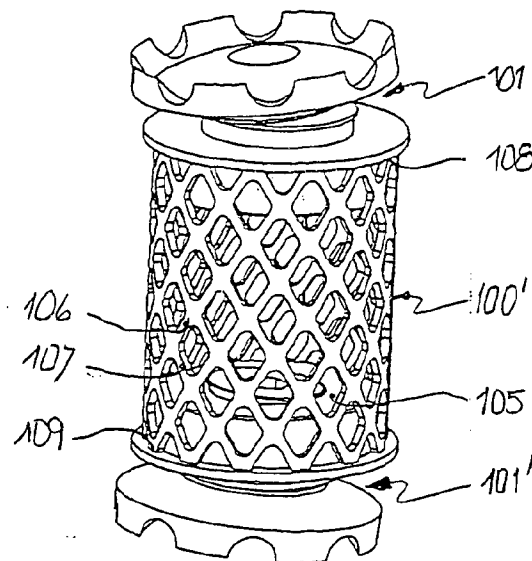


Fig. 2

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Beschreibung

[0001] Die Erfindung betrifft einen Platzhalter für Wirbelkörper oder Bandscheiben nach dem Oberbegriff des Patentanspruchs 1.

[0002] Aus der EP 0 268 115 B ist ein Platzhalter der eingangs beschriebenen Art bekannt. Dieser dient insbesondere zum Ersetzen eines Wirbels. Dabei greifen die freien Enden des zylindermantelförmigen Elementes des Platzhalters in die jeweils benachbarten Wirbelkörper ein, so daß eine Fusion zwischen den beiden angrenzenden Wirbelkörpern und dem dazwischenliegenden Platzhalter erfolgt.

[0003] Aus der DE 43 23 034 ist ein Platzhalter der eingangs beschriebenen Art bekannt, der als Ersatz für eine entfernte Bandscheibe zwischen zwei benachbarte Wirbelkörper eingesetzt wird. Auch hier greift der Platzhalter mit seinen freien Enden in die benachbarten Wandungen der benachbarten Wirbelkörper ein, und es erfolgt eine Fusion zwischen den zwei angrenzenden Wirbelkörpern und dem die entfernte Bandscheibe ersetzenden Platzhalter.

[0004] Aufgabe der Erfindung ist es, einen Platzhalter sowohl für Wirbelkörper als auch für Bandscheiben zu schaffen, der die Eigenschaften der oben als bekannt beschriebenen Platzhalter aufweist und mit dem eine bewegliche Verbindung zwischen dem Platzhalter und dem angrenzenden Wirbelkörper möglich ist.

[0005] Diese Aufgabe wird durch den im Patentanspruch 1 gekennzeichneten Platzhalter gelöst.

[0006] Die Weiterbildungen der Erfindung sind in den Unteransprüchen gekennzeichnet.

[0007] Weitere Merkmale und Zweckmäßigkeiten der Erfindung ergeben sich aus der Beschreibung von Ausführungsbeispielen anhand der Figuren. Von den Figuren zeigen:

Figur 1 eine perspektivische Seitenansicht eines Platzhalters mit einem beweglichen Element auf einer Seite;

Figur 2 eine perspektivische Seitenansicht eines Platzhalters mit beweglichen Elementen an jedem Ende;

Figur 3 eine Schnittdarstellung durch eine erste Ausführungsform;

Figur 4 eine Schnittdarstellung durch eine zweite Ausführungsform;

Figur 5 eine Schnittdarstellung durch eine dritte Ausführungsform;

Figur 6 eine Schnittdarstellung durch eine vierte Ausführungsform;

Figur 7 eine Schnittdarstellung durch eine fünfte

Ausführungsform;

Figur 8 eine Schnittdarstellung durch eine sechste Ausführungsform;

Figur 9 eine Draufsicht auf eine der Ausführungsformen nach den Figuren 5 bis 8, teilweise geschnitten;

Figur 10 ein Detail aus Figur 9 mit vergrößertem Maßstab in einer ersten Stellung;

Figur 11 das in Figur 10 gezeigte Detail in einer zweiten Stellung.

[0008] Figur 1 zeigt eine Ausführungsform, bei der ein rohrförmiger Abschnitt 100 so ausgebildet ist, daß er im Verhältnis zu seinem Durchmesser relativ kurz ist. An seinem einen Ende weist der rohrförmige Abschnitt 100 ein Element 101 auf, welches eine Deckplatte 102 aufweist, die relativ zu dem rohrförmigen Abschnitt beweglich ausgebildet ist. Sowohl die Deckplatte als auch der rohrförmige Abschnitt weisen an ihren freien Enden Zacken 103, 104 auf, die zum Eingreifen in die benachbarten Wirbelkörperendflächen vorgesehen sind. Ein solches Element mit kurzem rohrförmigen Abschnitt ist insbesondere für den Ersatz einer entfernten Bandscheibe bestimmt.

[0009] In Figur 2 ist der rohrförmige Abschnitt 101' länger ausgebildet und nicht nur an einem Ende wie in Figur 1, sondern auch an dem gegenüberliegenden Ende mit einem Element mit entsprechender Deckplatte verbunden. Die Ausbildung der beiden Elemente 101 und 101' ist vorzugsweise identisch. Diese Ausführungsform dient aufgrund der entsprechenden Länge des rohrförmigen Elementes 101' insbesondere als Ersatz für einen oder mehrere Wirbel. Wie aus den Figuren 1 und 2 ersichtlich ist, weisen die rohrförmigen Abschnitte 100, 100' Ausnehmungen 105 auf, um ein Einwachsen von Knochenmaterial zu erleichtern. In den Figuren ist eine besonders bevorzugte Ausführungsform gezeigt. Der rohrförmige Abschnitt 100 bzw. 100' ist als zylindrisch ausgebildeter Mantel geformt und weist sich mit ihrer Längsdiagonalen parallel zur Mantelachse erstreckende rautenförmige Ausnehmungen 105 auf. Jeweils benachbarte Reihen solcher Rauten sind in Richtung der Mantelachse um eine halbe Rautenhöhe versetzt. Dadurch wird ein Netz von sich unter einem spitzen Winkel schneidenden Bandstreifen 106, 107 gebildet, die unter jeweils gleich großen Winkeln gegen die Längsdiagonale der Rauten geneigt sind. Der obere Rand 108 und der untere Rand 109 erstrecken sich jeweils in einer Ebene senkrecht zu der Längsachse 2.

[0010] Im weiteren werden anhand der Figuren 3 bis 11 verschiedene Ausführungsformen der zusammen mit dem jeweiligen rohrförmigen Abschnitt einen Platzhalter bildenden Elemente beschrieben.

[0011] Wie aus den Figuren ersichtlich ist, weist jede

Ausführungsform der Elemente eine Grundplatte und einer dieser gegenüberliegende Deckplatte auf.

[0012] Bei dem in Figur 3 gezeigten Ausführungsbeispiel ist die Grundplatte 71 als Zylinderelement ausgebildet, welches auf seiner der Deckplatte 72 zugewandten Seite eine Fläche mit einem ebenen Rand aufweist, deren Durchmesser gleich dem Durchmesser der Deckplatte 72 ist. Auf seiner der Deckplatte abgewandten Seite schließt sich ein zylindrischer Abschnitt 73 an, dessen Durchmesser ein wenig kleiner ist, so daß der darüberliegende Abschnitt mit größerem Durchmesser einen Anschlag bildet. Der Abschnitt 73 dient zum Aufnehmen eines rohrförmigen Abschnittes 100. Der rohrförmige Abschnitt 100 wird im Paßsitz auf den Abschnitt 73 aufgesetzt und weist an seinem freien Ende mit dem benachbarten Wirbelkörper in Eingriff bringbare Zacken 104 auf. Ferner weist der rohrförmige Abschnitt die oben beschriebenen Ausnehmungen 105 auf, die die Einwachsmöglichkeit wesentlich verbessern.

[0013] Die Grundplatte 71 weist auf ihrer der Deckplatte 72 zugewandten Seite eine zentral angeordnete konvexe Kontaktfläche 74 auf, die vorzugsweise sphärisch ausgebildet ist. Diese konkave Kontaktfläche ist von einem ebenen Rand umgeben. Die Deckplatte 72 weist eine Außenfläche 76 auf, die in dem gezeigten Ausführungsbeispiel eben ausgebildet ist und die an ihrem äußeren Rand sich nach außen zu der Außenfläche vertikal streckende Zacken 103 aufweist, die zum Eingreifen in eine benachbarte Wandung einer Wirbelkörperenplatte dienen. Auf der der Außenfläche 76 gegenüberliegenden Innenfläche weist die Deckplatte eine konkave Ausnehmung 77 auf, deren Ausbildung kongruent zur konvexen Kontaktfläche 74 ausgebildet ist. Angrenzend an die konkave Ausnehmung 77 und um diese herumlaufend erstreckt sich eine zu der Außenfläche 76 parallele Randzone 78. Wie weiter aus Figur 3 ersichtlich ist, weist die Randzone 78 auf der der Grundplatte zugewandten Unterseite benachbart zu der konkaven Ausnehmung 77 eine ringförmige Ausnehmung 79 auf. Diese weist in dem gezeigten Ausführungsbeispiel einen kreissegmentförmigen Querschnitt auf. Der dem gegenüberliegende ebene Rand 75 weist eine den gleichen Durchmesser aufweisende ringförmige Ausnehmung auf, die ebenfalls einen kreissegmentförmigen Querschnitt besitzt. In dem so gebildeten Paar der ringförmigen Ausnehmungen ist ein Ring angeordnet.

[0014] Bei der in Figur 4 gezeigten weiteren Ausführungsform stimmt die Ausbildung der Deckplatte mit der Deckplatte 72 vollständig überein. Die Grundplatte 71' unterscheidet sich von der zuvor beschriebenen Grundplatte 71 dadurch, daß anstelle der konvexen Kontaktfläche 74 eine konkave Kontaktfläche 81 vorgesehen ist, die in ihrer sphärischen Krümmung mit der konkaven Kontaktfläche 77 der Deckplatte 72 übereinstimmt. In allen übrigen Merkmalen stimmen die Grundplatte und der rohrförmige Abschnitt mit dem zuvor beschriebenen Ausführungsbeispiel überein.

[0015] Zwischen Grundplatte 71' und Deckplatte 72 liegt ein Kern 83. Dieser weist einen zur Symmetrieachse 8 symmetrisch angeordneten Zentralteil 9 auf, der die Form einer bikonvexen Linse aufweist und dessen jeweils konvexe Außenflächen die gleiche Krümmung und insbesondere sphärische Krümmung aufweisen, wie die damit zusammenwirkenden Kontaktflächen 74 und 77 der Grundplatte und der Deckplatte.

[0016] Wie die Figur weiter zeigt, weist auch der Kern 9 eine Randzone 10 auf, deren Außendurchmesser gleich dem Durchmesser von Grundplatte und Deckplatte ist. Die Randzone ist vorzugsweise so ausgebildet, daß die beiden der Grundplatte und der Deckplatte zugewandten Flächen zueinander und zu der Symmetrieebene des Kernes parallel ausgebildet sind. Auch die Randzone 10 weist auf beiden Seiten jeweils eine ringförmige Ausnehmung 11, 11' auf. Diese weisen den gleichen kreissegmentförmigen Querschnitt auf, wie die ringförmigen Ausnehmungen von Grundplatte und Deckplatte. Sowohl zwischen Grundplatte und Kern 9 als auch zwischen Kern und Deckplatte sind in den Rillen jeweils Ringe 80, 80' angeordnet.

[0017] Bei den oben beschriebenen Ausführungsformen sind Grundplatte und Deckplatte jeweils aus einem biokompatiblen Material, insbesondere Stahl oder Titan hergestellt. Der Kern bei der in Fig. 4 gezeigten Ausführungsform ist aus einem körperverträglichen hochmolekularen Polyethylenkunststoff geformt. Die beiden Ringe 80, 80' sind aus einem körperverträglichen elastischen Kunststoff, beispielsweise Medical Grade Silikonummi gebildet. Bei den in den Figuren 5 und 6 gezeigten Ausführungsformen sind die elastische Zwischenschicht 29 beziehungsweise der Ring 48 ebenfalls aus einem körperverträglichen elastischen Kunststoff, beispielsweise Medical Grade Silikonummi hergestellt. Der rohrförmige Abschnitt 100 ist vorzugsweise aus Titan oder einem anderen körperverträglichen Material geformt.

[0018] Die in der Fig. 5 gezeigte dritte Ausführungsform weist wiederum eine Grundplatte 21, eine Deckplatte 22 und dazwischen einen Kern 23 auf.

[0019] Die Grundplatte 21 weist auf ihrer dem Kern 23 zugewandte Oberfläche symmetrisch zur Symmetrieachse 8 eine der konkaven Ausnehmung 81 entsprechende konkave Ausnehmung 26 auf. Es ist eine erste Randzone 27 vorgesehen, die anders als beim zweiten Ausführungsbeispiel aber nicht eben, sondern zur Außenseite der Grundplatte hin kegelstumpfförmig abfallend ausgebildet ist.

[0020] Die dem Kern 23 abgewandte Seite der Grundplatte 21 sowie die Verbindung mit dem rohrförmigen Abschnitt 100 ist genauso ausgebildet wie bei den vorher beschriebenen Ausführungsformen.

[0021] Die Deckplatte 22 weist wiederum nach außen hervorstehende Zacken 25 auf. Die Außenfläche 24' ist, wie am besten aus Fig. 5 ersichtlich ist, als konvexe kugelsegmentförmige Oberfläche ausgebildet, wobei die Krümmung der Oberfläche so gewählt ist, daß sie im

wesentlichen einer typischen konkaven Krümmung einer damit in Kontakt zu bringenden Wirbelkörperendplattenfläche entspricht.

[0022] Die dem Kern 23 zugewandte Seite der Deckplatte 22 ist genauso ausgebildet wie die dem Kern zugewandte Seite der Grundplatte 21.

[0023] Der Kern 23 ist dreiteilig ausgebildet und besteht aus zwei mit ihren Planflächen einander zugewandten plan-konvexen Linsenkörpern 28, 28', zwischen denen eine plan-parallele Platte 29 angeordnet ist. Die Linsenkörper 28, 28' und die Platte 29 haben im wesentlichen den gleichen Durchmesser. Die Krümmung der konvexen Flächen der Linsenkörper entspricht der Krümmung der damit zusammenwirkenden konkaven Ausnehmungen 26, 26'.

[0024] Wie am besten aus Fig. 5 ersichtlich ist, weist der Kern 23 eine sich senkrecht zu seiner Symmetrieebene erstreckende und durch seinen Mittelpunkt gehende Bohrung 30 auf. An den entsprechenden Stellen weisen Grundplatte und Deckplatte sich entlang ihrer Symmetriachsen erstreckende durchgehende Ausnehmungen 31, 31' auf. Auf den jeweiligen den Außenflächen 24, 24' zugewandten Seiten sind diese durch Senkbohrungen 32, 32' in ihrem Durchmesser erweitert. In der Bohrung 30 ist eine vorzugsweise aus einem körperverträglichen Kunststoff oder aus Metall gefertigte Verbindungshülse 33 vorgesehen, deren Durchmesser kleiner ist als der Durchmesser der Bohrung 30 und deren Länge größer als die Länge der Bohrung 30 ist, so daß die Verbindungshülse mit dem jeweiligen freien Ende in die Ausnehmung der benachbarten Platte eingreift. Wie aus Fig. 5 ersichtlich ist, ist die Hülse zu ihren Enden hin jeweils verjüngt ausgebildet. Von beiden Seiten ist jeweils durch die Ausnehmungen 31 geführt eine Schraube 34, 34' in die Verbindungshülse 33 eingeschraubt, wobei der Kopf der Schraube stets in der Senkbohrung anliegt. Die Senkbohrung ist ein wenig größer als der jeweilige Kopf. Die Schrauben werden so weit angezogen, daß Grund- und Deckplatte und Kern so miteinander verbunden sind, daß die aneinander grenzenden Flächen ohne Spiel, aber zueinander beweglich gehalten sind.

[0025] Wie aus Fig. 5 ersichtlich ist, ist die Tiefe der Senkbohrungen 32, 32' etwas größer als die Dicke der Köpfe der Schrauben 34, 34'. Die Senkbohrungen sind an ihrem äußeren Ende jeweils durch Abdeckplatten 35 nach außen hin abgedeckt. Der Unterschied zwischen der Tiefe der Senkbohrungen 32, 32' und der Dicke der Köpfe der Schrauben 34, 34' ist so gewählt, daß die Köpfe beim federnden Zusammendrücken der Bandscheibenprothese gerade noch nicht an die Abdeckplatten 35 stoßen.

[0026] Die in Fig. 6 gezeigte Ausführungsform unterscheidet sich von der in Fig. 5 gezeigten Ausführungsform nur durch die Ausbildung des Kernes. Alle übrigen Teile stimmen mit der zuvor beschriebenen Ausführungsform überein.

[0027] Der Kern 43 weist wiederum zwei äußere plan-

konvexe Linsenkörper 48, 48' auf, die mit ihren konvexen Flächen in gleicher Weise wie vorher beschrieben mit den Grund- und Deckplatten zusammenwirken. Auch die zentrale Bohrung und die Befestigung mittels der Verbindungshülse und den Schrauben stimmt identisch überein. Anders als bei dem vorherigen Ausführungsbeispiel ist anstelle der plan-parallelen Platte 29 ein elastischer Ring 49 vorgesehen. Zur Aufnahme und Führung des Ringes 49 weisen die einander zugewandten planen Flächen der Linsenkörper 48, 48' im Querschnitt kreissegmentförmige ringförmige Ausnehmungen 50, 50' auf, in denen der Ring 49 gehalten ist.

[0028] Bei der in Fig. 7 gezeigten weiteren Ausführungsform stimmt die Deckplatte mit der in Fig. 5 beschriebenen Deckplatte überein.

[0029] Die Grundplatte 21' unterscheidet sich von der in den Figuren 5 und 6 gezeigten Grundplatte lediglich dadurch, daß die der Deckplatte 22 zugewandte Oberfläche 57 eben ausgebildet ist. In allen anderen Merkmalen stimmen die Grundplatte 21', der rohrförmige Abschnitt 100, sowie die Deckplatte 22 mit den anhand der Figuren 5 und 6 beschriebenen Ausführungsbeispielen überein.

[0030] Zwischen Grundplatte 21' und Deckplatte 22 ist wiederum ein Kern vorgesehen, der auf seiner der Deckplatte 22 zugewandten Seite einen plan-konvexen linsenförmigen Abschnitt 28 aufweist, der mit dem entsprechenden Abschnitt von Ausführungsform gemäß Figur 5 übereinstimmt. Zwischen diesem und der ebenen Fläche 57 der Grundplatte 21' ist eine plan-parallele Platte 29 vorgesehen. Die Materialien von Grundplatte und Deckplatte und linsenförmigen Körper 28 sind identisch mit den zuvor beschriebenen Ausführungsbeispielen. Die Materialwahl der plan-parallelen Platten 29 stimmt mit der der plan-parallelen Platten 29 aus Fig. 5 überein.

[0031] Die Grundplatte 91 unterscheidet sich gegenüber der in Fig. 7 beschriebenen Grundplatte 21' dadurch, daß sie unmittelbar um die Bohrung 30 herum eine ringförmige Ausnehmung mit einem kreissegmentförmigen Querschnitt aufweist. Anstelle des Kernes des zuvor beschriebenen Ausführungsbeispiels ist ein plan-konvexer Linsenkörper 48' vorgesehen, der mit seiner konvexen phärischen Oberfläche mit der Kontaktfläche der Deckplatte 22 zusammenwirkt und der auf seiner der Grundplatte zugewandten ebenen Fläche eine ringförmige Ausnehmung 50' aufweist, die in ihren Abmessungen denen der Ausnehmung 92 entspricht. Es ist ein Ring 49 vorgesehen, der in diesen beiden ringförmigen Ausnehmungen gelagert ist.

[0032] Die Materialien von Grundplatte und Deckplatte und Linsenkörper des Kernes stimmen mit denen des zuvor beschriebenen Ausführungsbeispiels überein. Der Ring 49 stimmt in seiner Materialauswahl mit dem Material der plan-parallelen Platte 29 des zuvor beschriebenen Ausführungsbeispiels überein.

[0033] In Fig. 9 ist eine Draufsicht auf eine Deckplatte der in den Fig. 5 bis 8 beschriebenen Ausführungsfor-

men gezeigt, wobei die Abdeckplatte 35' und der Kopf der Schraube 34' weggelassen sind.

[0034] Aus Fig. 9 ist zu ersehen, daß die jeweilige Hülse 33 an ihren jeweils verjüngt abgeschrägten Enden sechskantig ausgebildet ist, wobei die Flächen zwischen den sechs Ecken jeweils hohlkehlenartig ausgebildet sind. Die diesen sechskantigen Abschnitt aufnehmende jeweilige Ausnehmung 31' ist ebenfalls sechskantig ausgebildet, wobei der jeweilige Durchmesser durch zwei gegenüberliegende Ecken jeweils um ein vorbestimmtes Maß wenig größer als der entsprechende Durchmesser der Verbindungshülse an dieser Stelle ist. Die Flächen zwischen jeweils zwei Ecken sind zur Mitte der Ausnehmung hin bauchig ausgebildet, wobei der Radius der bauchigen Krümmung jeweils um ein vorbestimmtes Maß wenig größer als der Radius der Hohlkehlen ist.

[0035] Wie in Fig. 10 und Fig. 11 gezeigt ist, kann somit eine Drehung um ein durch die Größenunterschiede vorbestimmtes Maß zwischen Hülse und Deckplatte bzw. Hülse und Grundplatte erfolgen. Damit wird eine Begrenzung der Drehung auf einen vorbestimmten Winkel erreicht.

[0036] Bei allen gezeigten Ausführungsformen können die Außenflächen von Grund- und Deckfläche rauh ausgebildet sein, um eine Verbesserung des Einwachsens zu erreichen.

[0037] Bei allen oben beschriebenen Ausführungsbeispielen können die aneinandergrenzenden und eine Relativbewegung zueinander ausführenden Flächen mit entsprechendem Material als Gleitpaarung beschichtet sein. Dafür kommen insbesondere Keramikschichten oder auch Polyethylenbeschichtungen oder auch entsprechende Metallegierungen in Frage.

[0038] Bei den oben beschriebenen Ausführungsformen sind jeweils aneinandergrenzende und zusammenwirkende konkave und konvexe sphärische Flächen beschrieben. Dabei hat jeweils der Kern die konvexen Flächen und die Deckplatte und die Grundplatte haben zugehörige konkave sphärische Flächen. Nach einer abgewandelten Ausführungsform können die Flächenformen jeweils umgekehrt sein. Das heißt, der Kern kann als bikonkaver Linsenkörper oder als plan-konkaver Linsenkörper ausgebildet sein und die zugehörige Kontaktfläche von Grundplatte und Deckplatte ist dann entsprechend zu der konkaven sphärischen Fläche sphärisch konvex ausgebildet.

[0039] Die zuvor anhand der Figuren 3 bis 8 beschriebenen Ausführungsbeispiele sind insbesondere als Bandscheibenersatz geeignet. Durch gitterartige Ausbildung des rohrförmigen Abschnittes 100 kann der Operateur diesen rohrförmigen Abschnitt auf eine gewünschte Länge zuschneiden, beispielsweise auf die relativ kurze in Fig. 1 gezeigte Länge. Anschließend wird der so als Bandscheibenprothese ausgebildete Platzhalter zwischen zwei Wirbelkörper eingesetzt und greift mit den Zacken in die benachbarten Wirbelkörperendplatten ein, so daß die Platten selbst drehfest ge-

halten werden. Die elastischen Ringe bewirken eine Abfederung der Bandscheibenprothese gegen zu starkes Verkippen und bremsen gleichzeitig ein zu starkes Verdrehen um die Mittenachse 8. Die elastische Platte bewirkt jeweils eine Stoßdämpfung in axialer Richtung. Bei der Anwendung wird der Außendurchmesser von Grund- und Deckplatte so gewählt, daß er ein wenig kleiner ist als der kleinste Durchmesser der benachbarten Wirbelkörperendplattenflächen.

[0040] Ist der Platzhalter zum Ersatz eines oder mehrerer Wirbelkörper gedacht, dann wird, wie in Fig. 2 gezeigt, ein oben beschriebenes Element nicht nur von einer Seite, sondern auch von der anderen Seite jeweils bevorzugt im Paßsitz in den rohrförmigen Abschnitt 100' eingefügt, so daß die dadurch vorhandenen beiden Deckplatten jeweils um die Mittenachse des rohrförmigen Abschnittes 100' in oben beschriebener Weise kippbar ausgebildet sind.

[0041] Bei der Anwendung wird der so ausgebildete Platzhalter nach Entfernen des geschädigten Wirbelkörpers und der zugehörigen Bandscheiben zwischen die verbleibenden beiden Wirbelkörper eingesetzt und greift mit den Zacken in die benachbarten Wirbelkörperendplatten, so daß die gegenüberliegenden Deckplatten drehfest gehalten werden. Die Funktion der einzelnen Elemente wie Ring und planparallele Platten aus Kunststoff erfolgt wie oben beschrieben.

[0042] Gewünschtenfalls können die Kontaktflächen zwischen Deckplatte und Kern bzw. Grundplatte und Kern jeweils mit Materialien beschichtet werden, die eine besonders gute Gleitpaarung ergeben.

Patentansprüche

1. Platzhalter für Wirbelkörper oder Bandscheiben mit einem rohrförmigen Abschnitt (100) und mit Zacken (103, 104) an den jeweiligen Enden des Platzhalters, **dadurch gekennzeichnet, daß** an einem Ende des Abschnittes ein Element (101) vorgesehen ist, welches eine Deckplatte (102) aufweist, die um einen Winkel zur Längsachse des Abschnittes kippbar ist.
2. Platzhalter nach Anspruch 1, **dadurch gekennzeichnet, daß** das Element eine der Deckplatte (72) gegenüberliegende Grundplatte (71) aufweist, wobei eine der Platten auf der anderen Platte zugewandten Seite eine konkave Kontaktfläche (77) und die andere Platte eine angrenzende konvexe Kontaktfläche (74) aufweisen.
3. Platzhalter nach Anspruch 2, **dadurch gekennzeichnet, daß** um eine der Kontaktflächen herum eine Rille vorgesehen ist, in der ein mit der gegenüberliegenden Kontaktfläche in Kontakt befindlicher elastischer Ring eingebettet ist.

4. Platzhalter nach Anspruch 3, **dadurch gekennzeichnet, daß** auch um die gegenüberliegende Kontaktfläche herum eine Rille vorgesehen ist, in die der Ring eingreift. 5
5. Platzhalter nach Anspruch 1, **dadurch gekennzeichnet, daß** das Element (101') eine der Deckplatte (72') gegenüberliegende Grundplatte (71') und einen dazwischenliegenden Kern (83) aufweist, wobei wenigstens eine der Platten auf der dem Kern zugewandten Seite eine erste konkave Kontaktfläche (77, 81) und der Kern wenigstens eine angrenzende erste konvexe Kontaktfläche aufweisen. 10
6. Platzhalter nach Anspruch 5, **dadurch gekennzeichnet, daß** um eine der Kontaktflächen herum eine Rille vorgesehen ist, in der ein mit der gegenüberliegenden Kontaktfläche in Kontakt befindlicher elastischer erster Ring eingebettet ist. 15
7. Platzhalter nach Anspruch 6, **dadurch gekennzeichnet, daß** auch um die gegenüberliegende Kontaktfläche herum eine Rille vorgesehen ist, in die der erste Ring eingreift. 20
8. Platzhalter nach Anspruch 6 oder 7, **dadurch gekennzeichnet, daß** auch um eine der zweiten Kontaktflächen herum eine Rille vorgesehen ist, in der ein mit der gegenüberliegenden Kontaktfläche in Kontakt befindlicher elastischer zweiter Ring eingebettet ist. 25
9. Platzhalter nach Anspruch 8, **dadurch gekennzeichnet, daß** auch um die mit dem zweiten Ring in Kontakt befindliche gegenüberliegende Kontaktfläche herum eine entsprechende Rille vorgesehen ist. 30
10. Platzhalter nach Anspruch 1, **dadurch gekennzeichnet, daß** das Element eine der Deckplatte (22) gegenüberliegende Grundplatte (21) und einen mit dieser in Kontakt befindlichen Kern (23) aufweist, der auf seiner der Grundplatte abgewandten Seite eine konvexe Oberfläche aufweist, daß die Deckplatte auf der dem Kern zugewandten Seite einen konkav ausgebildeten Abschnitt (26) aufweist, und daß der Kern eine der Grundplatte zugewandte elastische Schicht (29) und eine den konvexen Teil umfassende Gleitfläche umfaßt. 40 45 50
11. Platzhalter nach Anspruch 10, **dadurch gekennzeichnet, daß** auch die Grundplatte einen konkaven Abschnitt aufweist und der Kern angrenzend an die elastische Schicht eine mit dem konkaven Abschnitt in Eingriff befindliche konvexe Gleitfläche umfaßt. 55
12. Platzhalter nach Anspruch 11, **dadurch gekennzeichnet, daß** der Kern bikonvex ausgebildet ist und in seiner Mitte eine elastische Zwischenschicht besitzt.
13. Platzhalter nach einem der Ansprüche 10 bis 12, **dadurch gekennzeichnet, daß** entlang einer sich von der Grundplatte zur Deckplatte erstreckenden Mittenachse ein Dorn zum Begrenzen der Relativbewegung zwischen Grund- und Deckplatte um die Mittenachse herum vorgesehen ist.
14. Platzhalter nach einem der Ansprüche 1 bis 13, **dadurch gekennzeichnet, daß** jeweils die Kontaktflächen der Grund- bzw. Deckplatte konvex und die Kontaktflächen des Kerns konkav ausgebildet sind.
15. Platzhalter nach einem der Ansprüche 1 bis 14, **dadurch gekennzeichnet, daß** auch an dem anderen Ende des rohrförmigen Abschnittes (100') ein Element (101') nach einem der Ansprüche 2 bis 14 vorgesehen ist.
16. Platzhalter nach einem der Ansprüche 1 bis 15, **dadurch gekennzeichnet, daß** der rohrförmige Abschnitt eine Mehrzahl von über die Oberflächen verteilt angeordneten Durchbrechungen bzw. Ausnehmungen aufweist.
17. Platzhalter nach Anspruch 16, **dadurch gekennzeichnet, daß** die Ausnehmungen eine Mehrzahl von in Umfangsrichtung einander benachbarte rautenförmige Ausnehmungen umfassen.

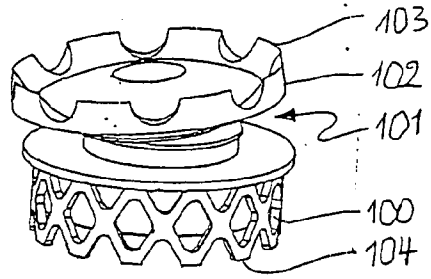


Fig. 1

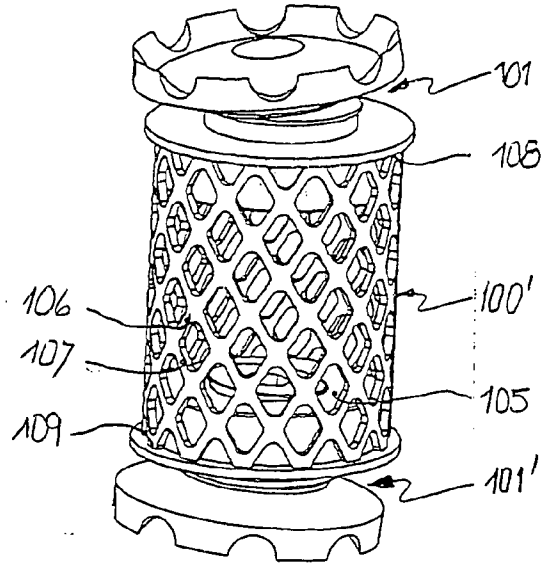


Fig. 2

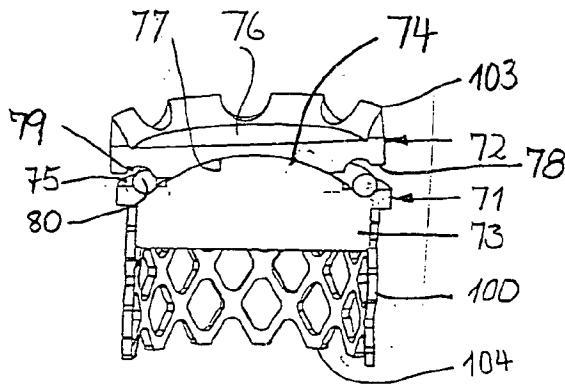


Fig. 3

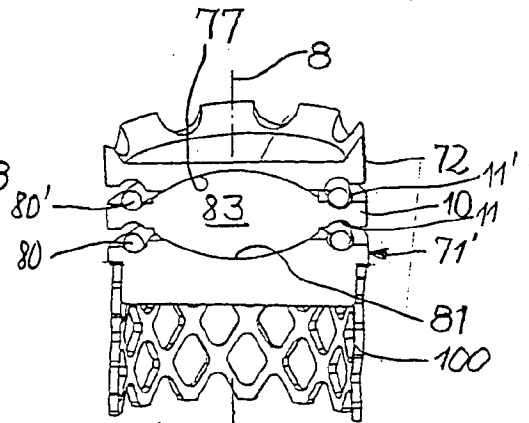
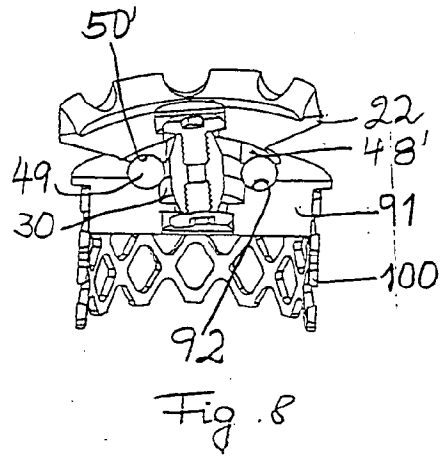
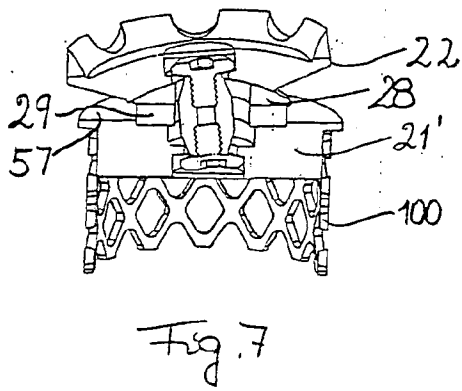
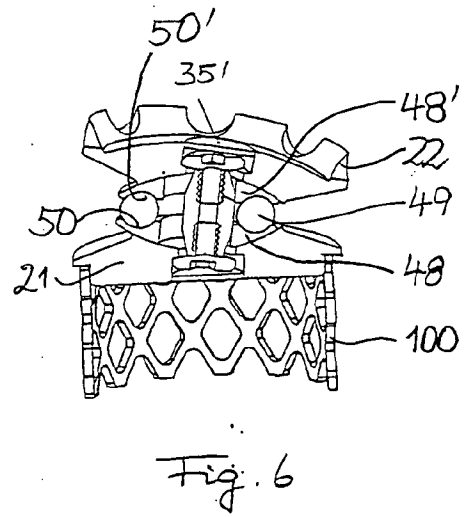
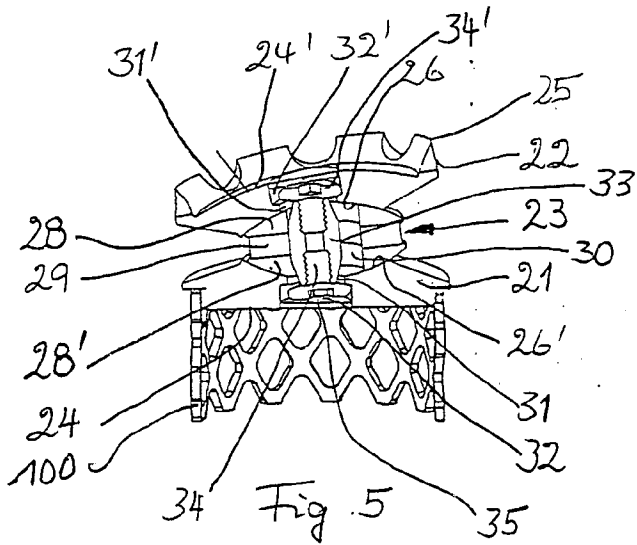


Fig. 4



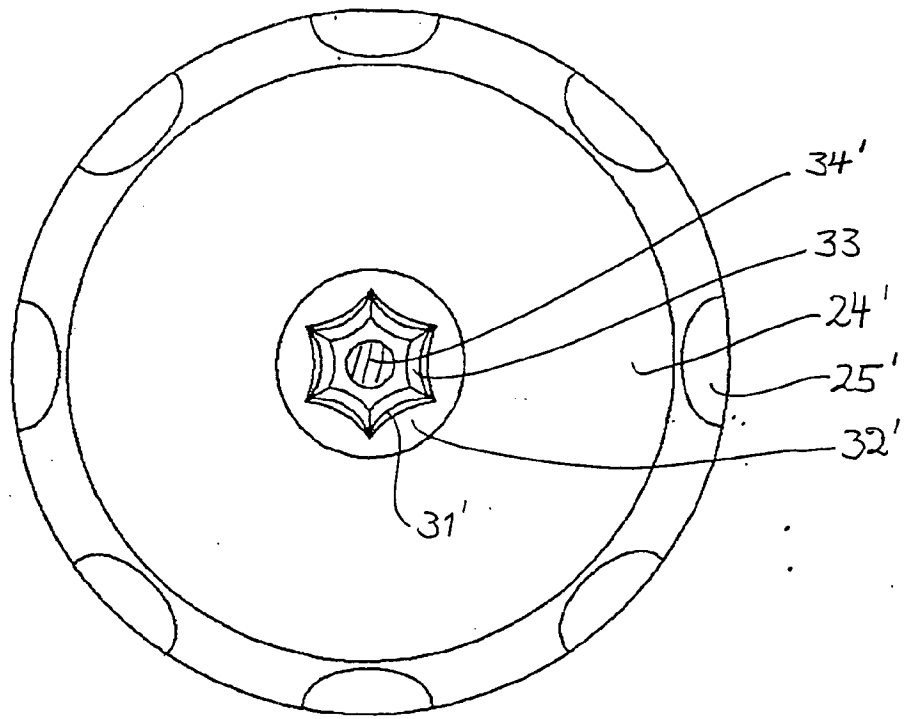


Fig. 9

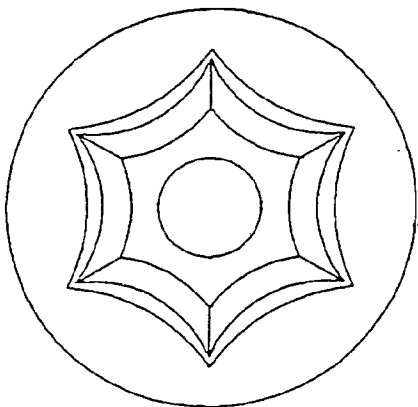


Fig. 10

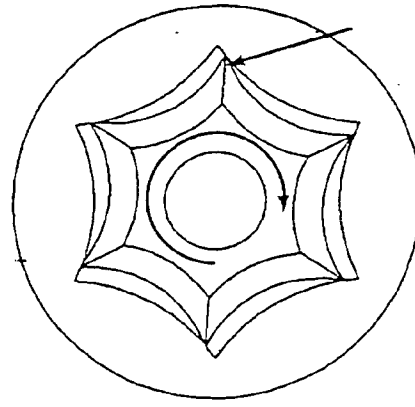


Fig. 11



Europäisches
Patentamt

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 03 01 7383

EINSCHLÄGIGE DOKUMENTE			
Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int.Cl.7)
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Rechenort	Abschlußdatum der Recherche	Prüfer	
BERLIN	19. Dezember 2003	Stach, R	
KATEGORIE DER GENANNTEN DOKUMENTE		T : der Erfindung zugrunde liegende Theorien oder Grundsätze E : älteres Patentdokument, das jedoch erst am oder nach dem Anmeldedatum veröffentlicht worden ist D : in der Anmeldung angeführtes Dokument L : aus anderen Gründen angeführtes Dokument & : Mitglied der gleichen Patentfamilie, übereinstimmendes Dokument	
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Europäisches
Patentamt

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 03 01 7383

EINSCHLÄGIGE DOKUMENTE			
Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int.Cl.7)
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Recherchenort BERLIN		Abschlußdatum der Recherche 19. Dezember 2003	
		Prüfer Stach, R	
<p>KATEGORIE DER GENANNTEN DOKUMENTE</p> <p>X : von besonderer Bedeutung allein betrachtet Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie A : technologischer Hintergrund O : mündliche Offenbarung P : Zwischenliteratur</p> <p>T : der Erfindung zugrunde liegende Theorien oder Grundsätze E : älteres Patentdokument, das jedoch erst am oder nach dem Anmeldedatum veröffentlicht worden ist D : in der Anmeldung angeführtes Dokument L : aus anderen Gründen angeführtes Dokument</p> <p>& : Mitglied der gleichen Patentfamilie, übereinstimmendes Dokument</p>			

EPO FORM 1503 03 82 (P04C03)

**ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT
ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR.**

EP 03 01 7383

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentedokumente angegeben.

Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am

Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

19-12-2003

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Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82

**ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT
 ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR.**

EP 03 01 7383

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentedokumente angegeben.

Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am
 Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

19-12-2003

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Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82



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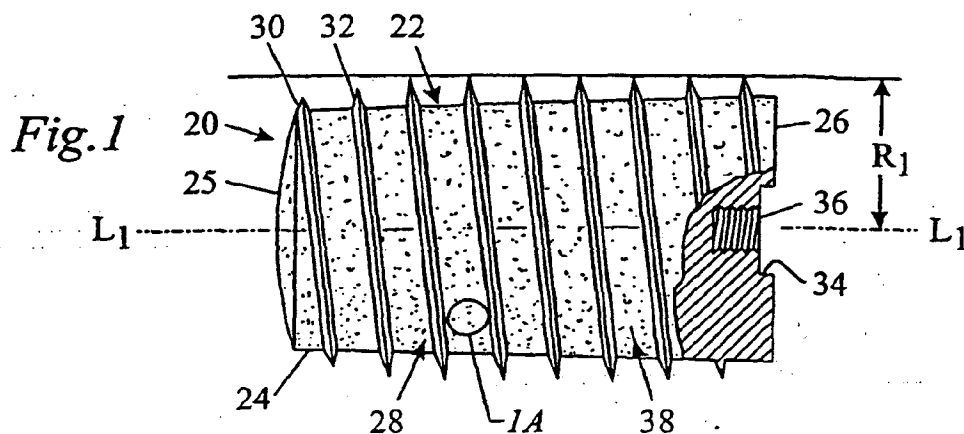
Remarks:

This application was filed on 25 - 11 - 2003 as a
divisional application to the application mentioned
under INID code 62.

(54) **An interbody spinal fusion implant having variable height threads**

(57) The present invention is directed to an interbody spinal fusion implant (20) for insertion across the surgically corrected height of the disc space between adjacent vertebral bodies of a human spine. A body (22) has an outer surface, an insertion end (24), a trailing

end (26), and a length between both ends (24,26), wherein the outer surface comprises a thread (28) for engaging said implant (20) to the adjacent vertebral bodies of the spine. This thread (28) has a thread height measured from said body (22), which is variable along a substantial portion of the length of the body.



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Description

[0001] This application is a continuation in part of co-pending United States application Serial No. 08/396,414 filed on February 27, 1995, which is a continuation-in-part of United States application Serial No. 07/698,674 filed on May 10, 1991 which is a divisional pf application Serial No. 07/205,935 filed on June 13, 1988, now United States Patent No. 5,015,247.

[0002] This application is also a continuation-in-part of United States application Serial No. 08/390,131 entitled Interbody Spinal Fusion Implants filed on February 17, 1995.

[0003] The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

[0004] Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space, the space between adjacent vertebrae normally occupied by a spinal disc. Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated with a loss of lordosis.

[0005] Therefore, there exists a need for spinal fusion implants that permit for the restoration of anatomical lordosis.

[0006] It is an object of the present invention to provide an interbody spinal fusion implant that is easily inserted into the spine and which maintains the anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process, wherein the implant is self-stabilizing within the spine and is capable of spacing apart the supporting adjacent vertebrae during the spinal fusion process.

[0007] This object is solved by the interbody spinal fusion implant with the features of claim 1.

[0008] Because of the spinal fusion implant of the present invention with variable thread height, insertion into the disc space is easily facilitated. The shape of the implant is consistent with the shape of the disc, which the implant at least in part replaces.

[0009] The spinal fusion implants of the present invention may be relatively solid and/or porous and/or hollow, and may have surface roughenings to promote bone in growth and stability.

[0010] If there are a number of openings passing through the body of the implant, these may pass either into or through the implant and may or may not intercept.

The spinal fusion implant of the present invention may also have at least one chamber, which may be in communication through at least one opening to the surface of the implant. Said chamber may have at least one access opening for loading the chamber with fusion promoting substances. This access opening may be capable of being closed with a cap or similar means.

[0011] If the implant is at least partially thrusto-conical in shape, those that taper from the leading edge to the trailing edge are easy to introduce and easy to fully insert into the spinal segment to be fused. In another embodiment where the trailing edge of the implant is larger than the leading edge, the implant utilizes a tapered forward portion and an increasing thread height relative to the body from the leading edge to the trailing edge to facilitate insertion.

[0012] The shape of the implant of the present invention is consistent with the shape of the disc, which the implant at least in part replaces, wherein the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.

[0013] The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt, chrome, stainless steel, or titanium, including its alloys, various plastics including those which are bio-absorbable, and various ceramics or combinations sufficient for the intended purpose. Further, the spinal fusion implants of the present invention may be made of a solid material, a mesh-like material, a porous material, and may comprise, wholly or in part, materials capable of directly participating in the spinal fusion process, or be loaded with, composed of, treated with, or coated with chemical substances such as bone, morphogenic proteins, hydroxyapatite in any of its forms, and osteogenic proteins, to make them bioactive for the purpose of stimulating spinal fusion. The implants of the present invention may be wholly or in part bio-absorbable.

[0014] Further advantages of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

Brief Description of the Drawings

[0015]

Figure 1 is a side elevational view of the spinal fusion implant of the present invention, having a body that is frusto-conical with an external thread having a substantially uniform radius.

Figure 1A is an enlarged fragmentary view along line 1A of figure 1 illustrating the surface configuration of the implant of figure 1.

Figure 1B is an enlarged fragmentary view along line 1A of figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

Figure 1C is a cross sectional view along lines 1C--1C of Figure 1B illustrating the alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

Figure 1D is an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material.

Figure 1E is a fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention comprising a plurality of spaced apart posts.

Figure 1F is an enlarged fragmentary sectional view along lines 1F--1F of Figure 1E illustrating the surface configuration of the implant of Figure 1E.

Figure 2 is an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body with an external thread radius and thread height that are not constant.

Figure 3 is a cross sectional view along line 3--3 of the implant of Figure 2.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention.

Figure 5 is a side elevational view and partial cut-away of a segment of the spinal column in lordosis showing the spinal fusion implant of Figure 4 being implanted with a driving instrument from the posterior approach to the spinal column.

Figure 6 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body and truncated sides.

Figure 7 is an end view along line 7--7 of the spinal fusion implant of Figure 6 shown placed beside a second identical implant shown in hidden line.

Figure 8 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body with an irregular configuration.

DETAILED DESCRIPTION OF THE DRAWINGS

[0016] Referring to Figure 1, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral 20 is shown. The implant 20 has a body 22 that is frusto-conical in shape such that the body 22 has a diameter (root diameter) that is generally frusto-conical. The body 22 has an insertion end 24 and a trailing end 26. The insertion end 24 may

include a tapered portion 25 to facilitate insertion of the spinal implant 20. In the preferred embodiment, when the implant 20 is inserted from the anterior aspect of the spine, the body 22 of the implant 20 has a maximum diameter at a point nearest to the trailing end 26 and a minimum diameter at a point nearest to the insertion end 24.

[0017] The implant 20 has an external thread 28 having a substantially uniform radius R_1 measured from the central longitudinal axis L_1 of the implant 20. The outer locus of the external thread 28 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_1 . While the major diameter of the implant 20 is substantially uniform, the external thread 28 may be modified at the leading edge by having initially a reduced thread radius to facilitate insertion of the implant 20 and may also be modified to make the external thread 28 self-tapping. In the preferred embodiment, the external thread 28 has a first thread 30 of a lesser radius than the radius R_1 of the remainder of the external thread 28 to facilitate insertion of the implant 20. The second thread 32 has a greater radius than the first thread 30, but is still shorter than the radius R_1 of the remainder of the external thread 28 which is thereafter of constant radius.

[0018] The body 22 is frusto-conical substantially along the portion of the body 22 in contact with the adjacent vertebrae of the spine which allows for creating and maintaining the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The substantially uniform radius R_1 of the external thread 28 of the implant 20 allows engaging the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant 20 from between the adjacent vertebrae in the direction opposite to which the implant 20 was implanted. The greater thread height measured from the body 22 near the leading end 24 of the implant 20 provides greater purchase into the vertebral bone and again enhances the stability of the implant 20. Further, the configuration of the external thread 28 increases the surface area of the implant 20 in contact with the vertebrae to promote bone ingrowth.

[0019] The implant 20 has a recessed slot 34 at its trailing end 26 for receiving and engaging insertion instrumentation for inserting the implant 20. The recessed slot 34 has a threaded opening 36 for threadably attaching the implant 20 to instrumentation used for inserting the implant 20.

[0020] Referring to Figure 1A, the implant 20 has an outer surface 38 that is porous to present an irregular surface to the bone to promote bone ingrowth. The outer surface 38 is also able to hold fusion promoting materials and provides for an increased surface area to engage the bone in the fusion process and to provide further stability. The pores of the outer surfaces 38 are microscopic in size having a diameter that is less than

1mm, in the range of 50-1000 microns, with 250-500 microns being the preferred diameter. It is appreciated that the outer surface 38, and/or the entire implant 20, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant 20 may be further coated with bioactive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins. The implant 20 is shown as being solid, however it is appreciated that it can be made to be substantially hollow or hollow in part.

[0021] Referring to Figure 1B, an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration 38 of the implant of the present invention made of a cancellous material is shown. The cancellous material 50, similar in configuration to human cancellous bone, having interstices 52 such that the outer surface 38 has a configuration as shown in Figures 1B and 1C. As the implant of the present invention may be made entirely or in part of the cancellous material 50, the interstices 52 may be present in the outer surface 38 and/or within the entire implant to promote bone ingrowth and hold bone fusion promoting materials.

[0022] Referring to Figure 1D, an enlarged fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a fibrous mesh-like material is shown. The mesh-like material 60 comprises strands 62 that are formed and pressed together such that interstices 64, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface 38 of implant of the present invention.

[0023] Referring to Figures 1E and 1F, a fragmentary view along line 1A of Figure 1 illustrating an alternative embodiment of the surface configuration 38 of the implant of the present invention comprising a plurality of spaced apart posts 70 is shown. The posts 70 have a head portion 72 of a larger diameter than the remainder of the posts 70, and each of the interstices 74 is the reverse configuration of the posts 72, having a bottom 76 that is wider than the entrance to the interstices 74. Such a configuration of the posts 70 and interstices 74 aids in the retention of bone material in the surface 38 of the implant and further assists in the locking of the implant into the bone fusion mass created from the bone ingrowth. As the bone ingrowth at the bottom 76 of the interstices is wider than the entrance, the bone ingrowth cannot exit from the entrance and is locked within the interstice 74. The surface of the implant provides for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

[0024] In the preferred embodiment, the posts 70 have a maximum diameter in the range of approximately

0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of approximately 0.1-2 mm such that the interstices 74 have a width in the range of approximately 0.1 to 2 mm. The post sizes, shapes, and distributions may be varied within the same implant.

[0025] In the preferred embodiment, for use in the lumbar spine, the implant 20 has an overall length in the range of approximately 24 mm to 32 mm with 26 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-20 mm, with 14-16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 26 in the range of 10-24 mm, with 16-18 mm being the preferred diameter at the trailing end 26, when said implants are used in pairs. When used singly in the lumbar spine, the preferred diameters would be larger.

[0026] In the preferred embodiment, the implant 20 has a thread radius R_1 in the range of 6 mm to 12 mm, with 9-10 mm being the preferred radius R_1 . For use in the cervical spine, the implant 20 has an overall length in the range of approximately 10-22 mm, with 12-14 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 8-22 mm, with 16-18 mm being the preferred root diameter at the insertion end when used singly, and 8-10 mm when used in pairs. The body 22 of the implant 20 has a root diameter at the trailing end 26 in the range of 10-24 mm, with 18-20 mm being the preferred root diameter at the trailing end 26 when used singly, and 10-12 mm when used in pairs; a thread radius R_1 in the range of approximately 4-12 mm, with 9-10 mm being the preferred radius R_1 when inserted singularly and 5-7 mm when inserted side by side in pairs.

[0027] Referring to Figure 2, an alternative embodiment of implant 20 is shown and generally referred to by the numeral 120. The implant 120 has a body 122 similar to body 22 of implant 20 and has an external thread 128 having a radius R_3 measured from the central longitudinal axis L_3 of the implant 120. The thread radius R_3 is not constant throughout the length of the implant 120 and the external thread 128 has a thread height that is also not constant with respect to the body 122 of the implant 120. In the preferred embodiment, the implant 120 has an external thread 128 with a radius R_3 that increases in size from the insertion end 124 to the trailing end 126 of the implant 120.

[0028] Referring to Figure 3, a cross sectional view along line 3-3 of the implant 120 is shown. The implant 120 has an outer wall 144 surrounding an internal chamber 146. The large and small openings 140 and 142 may pass through the outer wall 144 to communicate with the internal chamber 146. The internal chamber 146 may be filled with bone material or any natural or artificial bone growth material or fusion promoting material such that bone growth occurs from the vertebrae through the openings 140 and 142 to the material within internal chamber 146. While the openings 140 and 142 have

been shown in the drawings as being circular, it is appreciated that the openings 140 and 142 may have any shape, size configuration or distribution, suitable for use in a spinal fusion implant without departing from the scope of the present invention.

[0029] The openings 140 and 142 are macroscopic in size having a diameter that is greater than 1 mm. The large openings 140 have a diameter in the range of 26 mm, with the preferred diameter being 3.5mm; and the small openings have a diameter in the range of 1-2 mm, with 1.5 mm being the preferred diameter.

[0030] The implant 120 has a cap 148 with a thread 150 that threadably attaches to the insertion end 124 of the spinal fusion implant 120. The cap 148 is removable to provide access to the internal chamber 146, such that the internal chamber 146 can be filled with and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap 148 and/or the spinal fusion implant 120 may be made of any material appropriate for human implantation including metals such as cobalt chrome, stainless steel, titanium, plastics, ceramics, composites and/or may be made of, and/or filled, and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. The cap 148 and the implant 120 may be partially or wholly bioabsorbable.

[0031] Referring to Figure 4, a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention generally referred to by numeral 520 is shown. The implant 520 has a body 522 having a root diameter that is frusto-conical in the reverse direction as that of implant 20 shown in Figure 1, in order to preserve and/or restore lordosis in a segment of spinal column when inserted from the posterior aspect of the spine. The body 522 has an insertion end 524, and a trailing end 526. In the preferred embodiment, the body 522 of the implant 520 has a minimum diameter at a point nearest to the trailing end 526 and a maximum diameter at a point nearest to the insertion end 524. The insertion end 524 may have an anterior nose cone portion 530 presenting a tapered end to facilitate insertion.

[0032] The implant 520 has an external thread 528 having a substantially uniform radius R_6 measured from the central longitudinal axis L_6 of the implant 520, such that the external diameter of the external thread 528 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_6 . It is appreciated that the thread 528 can have a major diameter that varies with respect to the longitudinal axis L_6 , such that the major diameter may increase from the insertion end 524 to the trailing end 526 or the reverse. The external thread 528 has a thread height measured from

the body 522 that increases from the insertion end 524 to the trailing end 526.

[0033] Referring to Figure 5, a segment of the spinal column S is shown with the vertebrae V_1 and V_2 in lordosis and an implant 520 shown being inserted from the posterior aspect of the spinal column S with an instrument driver D. The implant 520 is inserted with the larger diameter insertion end 524 first in order to initially distract apart the vertebrae V_1 and V_2 which then, angle toward each other posteriorly as the implant 520 is fully inserted. It is appreciated that the insertion of implant 520 does not require the adjacent vertebrae V_1 and V_2 to be placed in lordosis prior to insertion, as the full insertion of the implant 520 itself is capable of creating the desired lordotic angular relationship of the two vertebrae V_1 and V_2 .

[0034] In the preferred embodiment, for use in the lumbar spine, the implant 520 has an overall length in the range of approximately 24 mm to 30 mm, with 26 mm being the preferred length. The body 522 of the implant 520 has a root diameter at the insertion end 524 in the range of 12-22 mm, with 16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 526 in the range of 10-20 mm, with 14 mm being the preferred diameter at the trailing end 526. In the preferred embodiment, the implant 520 has a thread radius R_6 in the range of 6 mm to 12 mm, with 8 mm being the preferred radius R_6 .

[0035] Referring to Figure 6, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral 620 and a partial fragmentary view of a second identical implant, generally referred to by the numeral 621 are shown. The implant 620 has a body 622 that is partially frusto-conical in shape similar to body 22 of implant 20 shown in Figure 1, and has an insertion end 624 and a trailing end 626. The body 622 of the implant 620 has truncated sides 670 and 672 forming planar surfaces that are parallel to the longitudinal axis L_7 . In this manner, two implants 620 and 621 may be placed side by side, with one of the sides 670 or 672 of each implant with little space between them, such that the area of contact with the bone of the adjacent vertebrae is maximized. It is appreciated that the body 622 may also be cylindrical in shape and have truncated sides 670 and 672.

[0036] The implant 620 has an external thread 628 having a radius R_7 measured from the central longitudinal axis

L_7 that may be constant, such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially cylindrical. It is appreciated that the external thread 628 may have a thread radius R_7 that is variable with respect to the longitudinal axis L_7 such that the major diameter or outer locus of the external thread 628 has an overall configuration that is substantially frusto-conical.

[0037] Referring to Figure 7, an end view of the implant 620 placed beside implant 621 is shown. The im-

plant 620 has a thread radius that is substantially constant and has a thread height measured from the body 622 that is greater at the sides 670 and 672. In this manner, two implants 620 and 621 can be placed beside each other with the external thread 628 of each implant interdigitated allowing for closer adjacent placement of the two implants as a result of the substantial overlap of the external thread 628 at the side 670 or 672 of the implants.

[0038] Referring to Figure 8, an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 700. The implant 700 is similar in configuration to implant 20 shown in Figure 1, except that the body 722 has an irregular configuration. The configuration of the body 722 has a root diameter D which is variable in size throughout the length of the implant 700 and, as shown in this embodiment, comprises larger diameter portions 750 and smaller diameter portions 752. It is appreciated that each of the large diameter portions 750 may be of the same or different diameter and each of the smaller diameter portions 752 may be of the same or different diameter.

[0039] The outer surface of the body 722 of implant 700 may be filled with fusion promoting substances such that the smaller diameter portions 752 may hold such fusion promoting substances. If so filled, the composite of the implant 700 and the fusion promoting material could still produce an even external surface of the body 722 if so desired.

[0040] While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

[0041] Each of the features disclosed in the various embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.

Claims

1. An interbody spinal fusion implant for insertion across the surgically corrected height of a disc space between adjacent vertebral bodies of a human spine, said implant comprising:

a body (22, 122, 522, 622) having an outer surface (38), an insertion end (24, 124, 524, 624), a trailing end (26, 126, 526, 626), and a length between said insertion end (24, 124, 524, 624) and said trailing end (26, 126, 526, 626), said

outer surface comprising a thread (28, 128, 528, 628) for engaging said implant to the adjacent vertebral bodies of the spine;

characterized in that said thread (28, 128, 528, 628) has a thread height measured from said body (22, 122, 522, 622) which is variable along a substantial portion of the length of said body (22, 122, 522, 622).

2. The implant of claim 1, wherein the thread height increases from said insertion end (124, 524, 624) towards said trailing end (126, 526, 626).
3. The implant of claim 1, wherein the thread height increases from said trailing end (26, 626) towards said insertion end (24, 624).
4. The implant of any one of the above claims, wherein said trailing end (26, 126, 626) is larger than said insertion end (24, 124, 624).
5. The implant of either claim 1 or 2, wherein said insertion end (524) is larger than said trailing end (526).
6. The implant of any one of the above claims, wherein said body (22, 122, 522, 622) has a substantially frustoconical configuration along a sufficient portion of said body (22, 122, 522, 622) to maintain angulation of the vertebral bodies relative to one another.
7. The implant of either claim 1 or 2, wherein said body has a substantially cylindrical configuration.
8. The implant of either claim 1 or 2, wherein said thread (128) has an outer locus that forms a substantially frustoconical configuration.
9. The implant of any one of claims 1-3, wherein said thread (28, 528, 628) has an outer locus that forms a substantially cylindrical configuration.
10. The implant of any one of the above claims, wherein said body has at least one opening (140, 142) passing therethrough so as to allow bone to grow from adjacent vertebral body to adjacent vertebral body through said implant.
11. The implant of claim 10, wherein said body includes an internal chamber (146) in communication with said at least one opening (140, 142).
12. The implant of any one of the above claims, wherein said body has at least one truncated side (670, 672).
13. The implant of claim 12, wherein said thread (628)

is continuous over at least a portion of said at least one truncated side (670, 672).

14. The implant of any one of the above claims, wherein said implant (620) is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant (621), said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants. 5 10
15. The implant of any one of the above claims, wherein said implant comprises a mesh-like material (60). 15
16. The implant of any one of the above claims, wherein said implant is at least in part bioabsorbable.
17. The implant of any one of the above claims, in combination with a fusion promoting substance. 20
18. The implant of claim 17, wherein said fusion promoting substance includes at least one of bone, bone morphogenetic protein, hydroxyapatite, and hydroxyapatite tricalcium phosphate. 25
19. The spinal fusion implant of any one of the above claims, in combination with a driver (D) for inserting said implant into the spine. 30

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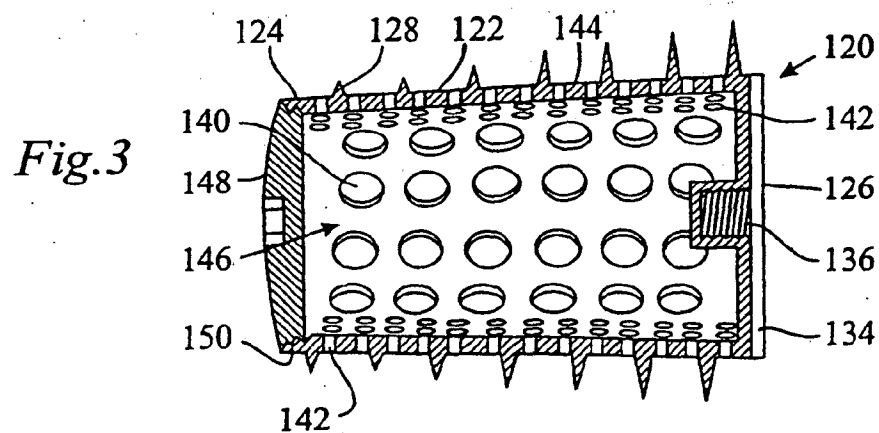
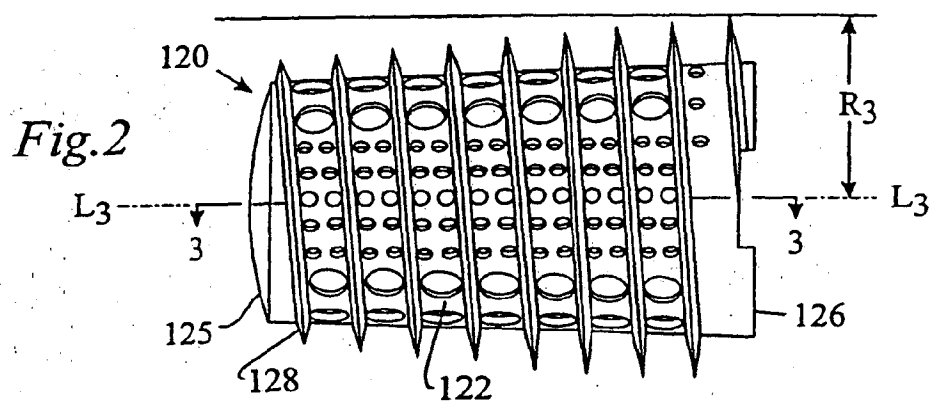
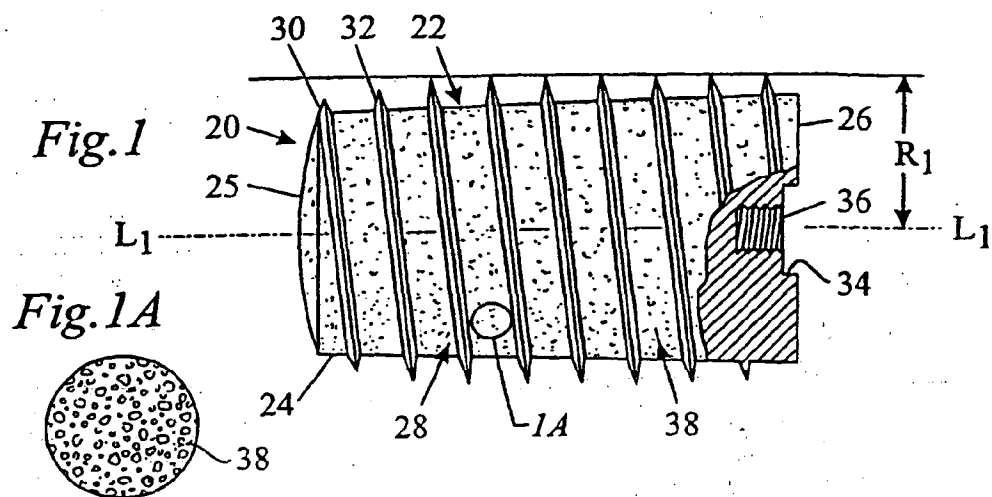
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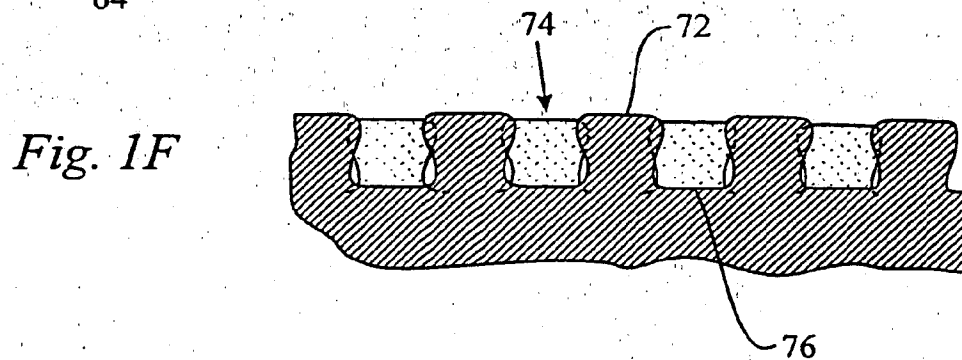
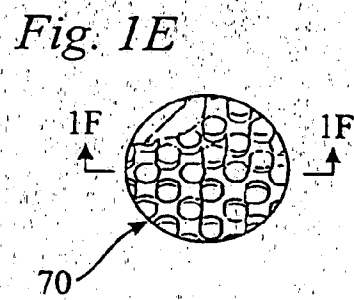
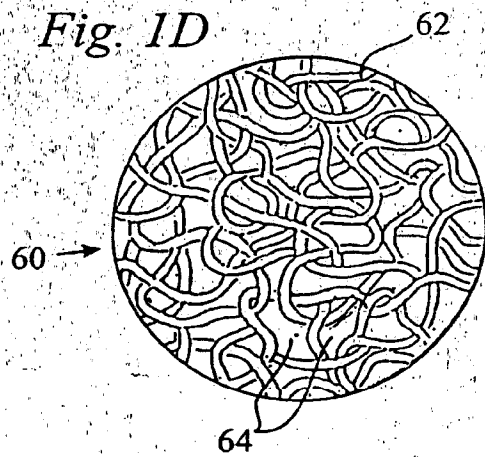
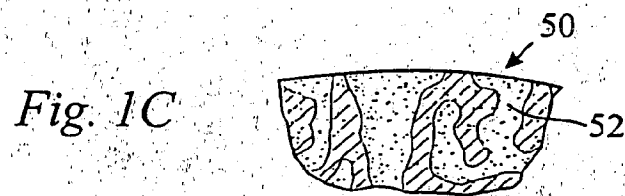
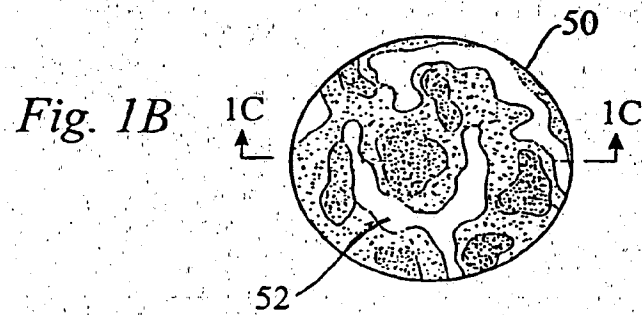


Fig. 4

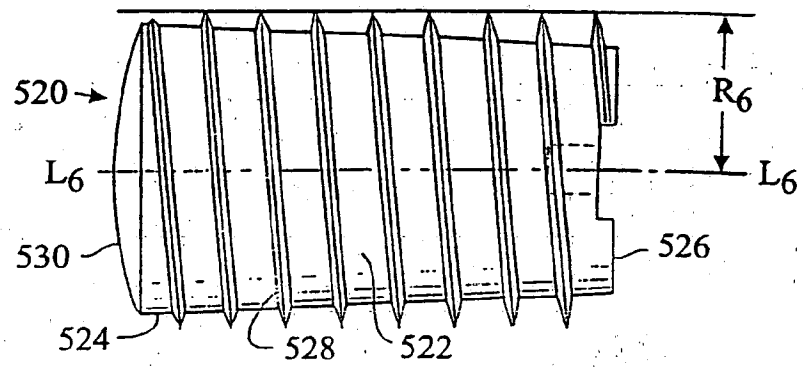
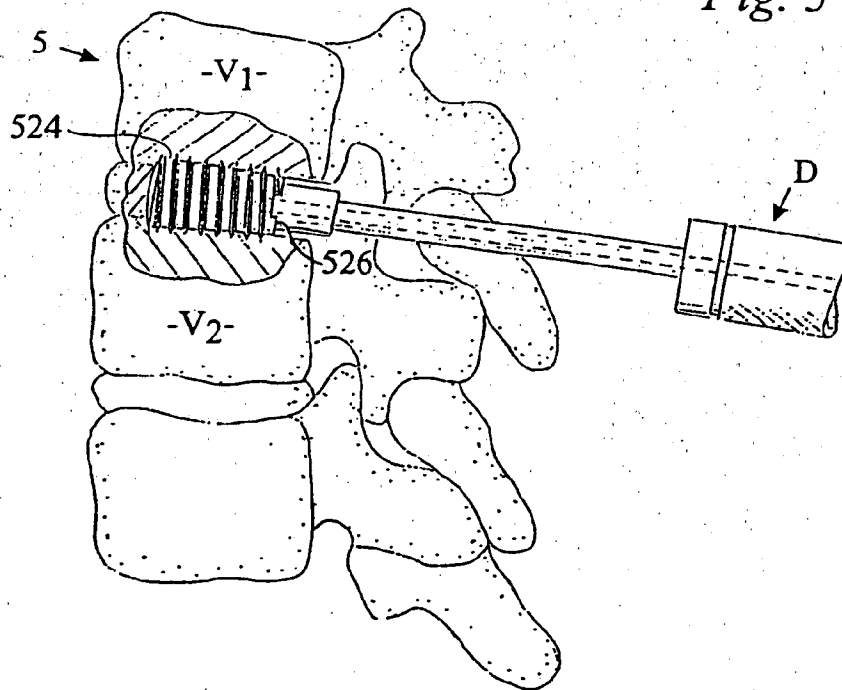
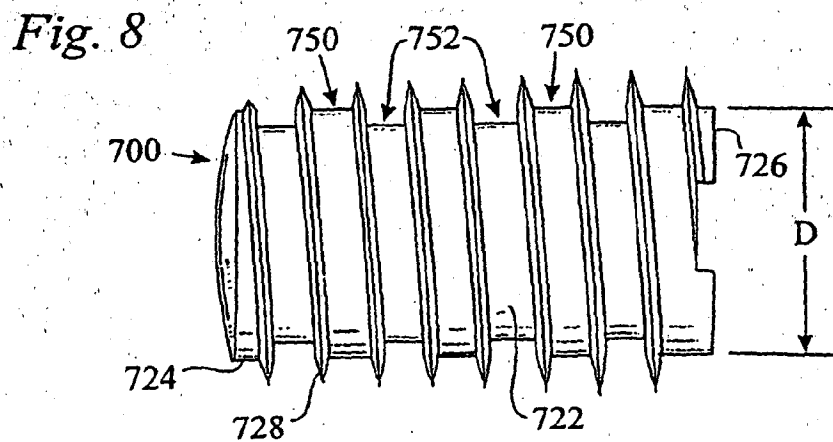
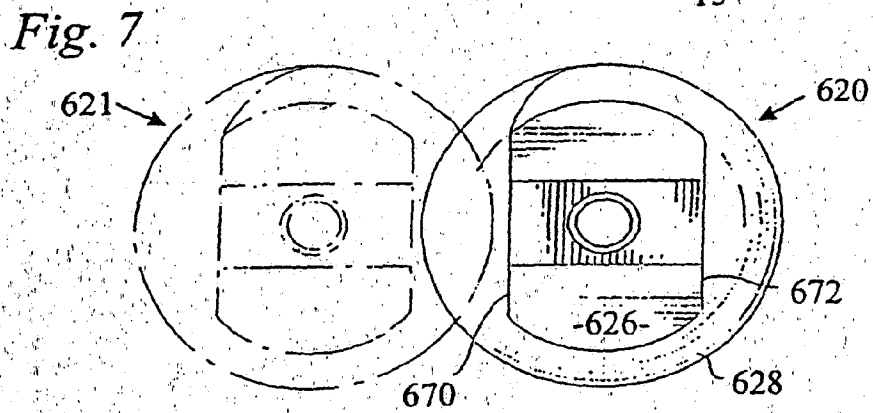
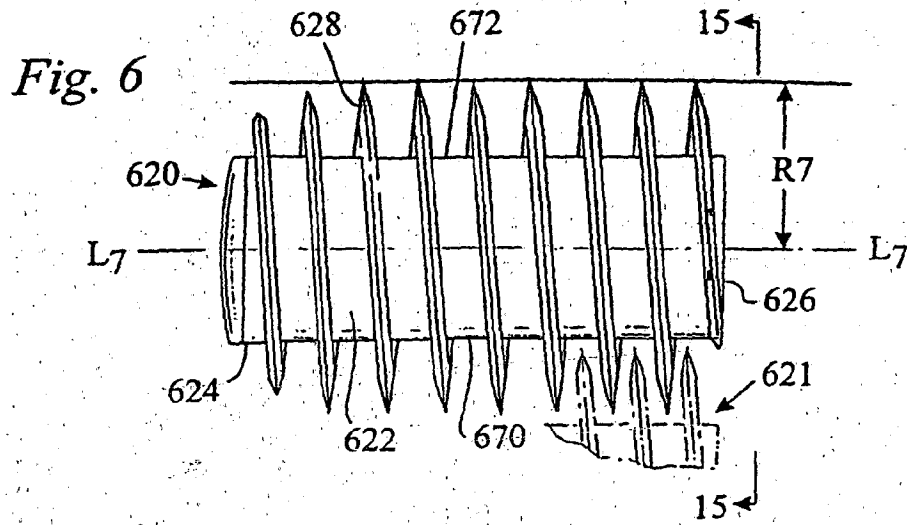


Fig. 5







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This application was filed on 27 - 11 - 2003 as a
divisional application to the application mentioned
under INID code 62.

(54) **Open intervertebral spacer**

(57) Open chambered spacers, implanting tools and methods are provided. The spacers (500') include a body (505') having a wall (506') which defines a chamber (530') and an opening (531') in communication with the chamber (530'). In one embodiment the wall (506') includes a pair of arms (520', 521') facing one another and forming a mouth (525') to the chamber (530'). Preferably, one of the arms (520') is truncated relative to the other, forming a channel (526'). In one aspect the body (505') is a bone dowel comprising an off-centre plug from the diaphysis of a long bone. The tools (800) include spacer engaging means for engaging a spacer and occlusion means for blocking an opening defined in the spacer. In some embodiments, the occlusion means (820) includes a plate (821) extendable from the housing (805). In one specific embodiment the plate (821) defines a groove (822) which is disposed around a fastener (830) attached to the housing (805) so that the plate (821) is slidable relative to the housing (805).

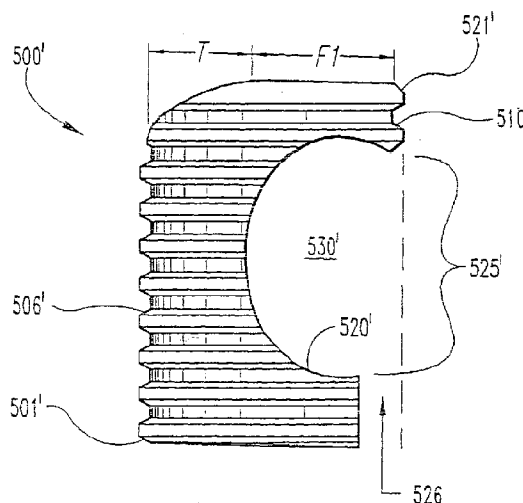


Fig. 10

Description

FIELD OF THE INVENTION

5 **[0001]** The present invention broadly concerns arthrodesis for stabilizing the spine. More specifically, the invention provides open-chambered intervertebral spacers, instruments for implanting the spacers and methods for making and using the spacers.

BACKGROUND OF THE INVENTION

10 **[0002]** Intervertebral discs, located between the endplates of adjacent vertebrae, stabilize the spine, distribute forces between vertebrae and cushion vertebral bodies. A normal intervertebral disc includes a semi-gelatinous component, the nucleus pulposus, which is surrounded and confined by an outer, fibrous ring called the annulus fibrosus. In a healthy, undamaged spine, the annulus fibrosus prevents the nucleus pulposus from protruding outside the disc space.

15 **[0003]** Spinal discs may be displaced or damaged due to trauma, disease or aging. Disruption of the annulus fibrosus allows the nucleus pulposus to protrude into the vertebral canal, a condition commonly referred to as a herniated or ruptured disc. The extruded nucleus pulposus may press on a spinal nerve, which may result in nerve damage, pain, numbness, muscle weakness and paralysis. Intervertebral discs may also deteriorate due to the normal aging process or disease. As a disc dehydrates and hardens, the disc space height will be reduced leading to instability of the spine, decreased mobility and pain.

20 **[0004]** Sometimes the only relief from the symptoms of these conditions is a discectomy, or surgical removal of a portion or all of an intervertebral disc followed by fusion of the adjacent vertebrae. The removal of the damaged or unhealthy disc will allow the disc space to collapse. Collapse of the disc space can cause instability of the spine, abnormal joint mechanics, premature development of arthritis or nerve damage, in addition to severe pain. Pain relief via discectomy and arthrodesis requires preservation of the disc space and eventual fusion of the affected motion segments.

25 **[0005]** Bone grafts are often used to fill the intervertebral space to prevent disc space collapse and promote fusion of the adjacent vertebrae across the disc space. In early techniques, bone material was simply disposed between the adjacent vertebrae, typically at the posterior aspect of the vertebra, and the spinal column was stabilized by way of a plate or rod spanning the affected vertebrae. Once fusion occurred, the hardware used to maintain the stability of the segment became superfluous and was a permanent foreign body. Moreover, the surgical procedures necessary to implant a rod or plate to stabilize the level during fusion were frequently lengthy and involved.

30 **[0006]** It was therefore determined that a more optimal solution to the stabilization of an excised disc space is to fuse the vertebrae between their respective end plates, preferably without the need for anterior or posterior plating. There have been an extensive number of attempts to develop an acceptable intradiscal implant that could be used to replace a damaged disc and maintain the stability of the disc interspace between the adjacent vertebrae, at least until complete arthrodesis is achieved. The implant must provide temporary support and allow bone ingrowth. Success of the discectomy and fusion procedure requires the development of a contiguous growth of bone to create a solid mass because the implant may not withstand the compressive loads on the spine for the life of the patient.

35 **[0007]** Several metal spacers have been developed to fill the void formed and to promote fusion. Sofamor Danek Group, Inc., (1800 Pyramid Place, Memphis, TN 38132, (800) 933-2635) markets a number of hollow spinal cages. For example, U.S. Patent No. 5,015,247 to Michelson and U.S. Serial No. 08/411,017 to Zdeblick disclose a threaded spinal cage. The cages are hollow and can be filled with osteogenic material, such as autograft or allograft, prior to insertion into the intervertebral space. Apertures defined in the cage communicate with the hollow interior to provide a path for tissue growth between the vertebral endplates.

40 **[0008]** Although the metal fusion devices of Sofamor Danek and others are widely and successfully employed for reliable fusions, it is sometimes desirable to use an all-bone product. Bone provides many advantages for use in fusions. It can be incorporated after fusion occurs and therefore will not be a permanent implant. Bone allows excellent postoperative imaging because it does not cause scattering like metallic implants. Stress shielding is avoided because bone grafts have a similar modulus of elasticity as the surrounding bone. Although an all-bone spacer provides these and other benefits, the use of bone presents several challenges. Any spacer which will be placed within the intervertebral disc space must withstand the cyclic loads of the spine. Cortical bone products may have sufficient compressive strength for such use, however, cortical bone will not promote rapid fusion. Cancellous bone is more conducive to fusion but is not biomechanically sound as an intervertebral spacer.

45 **[0009]** Several bone dowel products such as the Cloward Dowel have been developed over the years. Bone dowels in the shape of a generally circular pin can be obtained by drilling an allogeneic or autogeneic plug from bone. As shown in Figures 1 and 2, the dowels 100, 200 have one or two cortical surfaces 110 and an open, latticed body of brittle cancellous bone 120, 220 backing the cortical surface 210 or between the two cortical surfaces 110. The dowels

100, 200 also include a drilled and/or tapped instrument attachment hole 115, 215. Dowels and other bone products are available from the University of Florida Tissue Bank, Inc., (1 Innovation Drive, Alachua, Florida 32615, 904-462-3097 or 1-800-OAGRAFT; Product numbers 280012, 280014, and 280015).

[0010] While the bone dowels of the prior art are valuable bone grafting materials, these dowels have relatively poor biomechanical properties, in particular a low compressive strength. Accordingly, these dowels may not be suitable as an intervertebral spacer without internal fixation due to the risk of collapsing prior to fusion under the intense cyclic loads of the spine. A need remains for dowels having the advantages of allograft but with even greater biomechanical strength.

[0011] In response to this need, the University of Florida Tissue Bank, Inc., has developed a proprietary bone dowel machined from the diaphysis of long bones. Referring now to Figure 3, the dowel 300 includes a tool engagement end 301 and an opposite insertion end 302. Between the two ends 301 and 302, the dowel 300 includes a chamber 330 formed from the naturally occurring medullary canal of the long bone and an opening 331 in communication with the chamber 330. The chamber 330 can be packed with an osteogenic material to promote fusion while the cortical body 305 of the dowel 300 provides support. The dowels are also advantageous in that they provide desirable biomechanics and can be machined for various surface features such as threads or annular ribbing. In some embodiments, the outer cortical surface 310 of the tool engagement end 301 is machined with an instrument attachment feature and an alignment score mark. As shown in Figure 3, the insertion end 302 may include a chamfered portion 340.

[0012] While these diaphysial cortical dowels are a major advance in this field, a need has remained for bone dowels and other intervertebral spacers with greater versatility.

SUMMARY OF THE INVENTION

[0013] This invention provides spacers having an open chamber, tools for implanting the spacers and methods for making and using the spacers. The spacers include a body having a wall which defines a chamber and an opening in communication with the chamber. In one aspect, a channel is defined in the wall in communication with the chamber and the outer surface of the spacer. In another embodiment the wall includes a pair of arms facing one another and forming a mouth to the chamber. In a preferred embodiment, one of the arms is truncated relative to the other. In some aspects, the body is composed of bone. In one aspect the body is a dowel having a substantially C-shaped chamber and comprising an off-center bone plug obtained from the diaphysis of a long bone.

[0014] Tools for implanting spacers are also provided. The tools include spacer engaging means for engaging a spacer and occlusion means for blocking an opening defined in the spacer. In one aspect the engaging means includes a shaft slidably disposed within a housing and having a threaded post for engaging a threaded tool hole in the spacer. In some embodiments, the occlusion means includes a plate extendable from the housing. In one specific embodiment the plate defines a groove which is disposed around a fastener attached to the housing so that the plate is slideable relative to the housing.

[0015] This invention also includes methods for obtaining an open bone dowel and methods for using the spacers of this invention. The methods of making a dowel according to this invention include cutting an off-center plug from the diaphysis of a long bone to obtain a bone dowel having an open chamber. In one aspect, the dowel is machined to include desirable surface features such as threads, grooves and instrument holes. In still another aspect, the methods include chamfering the forward end of the dowel. The methods for using the spacers of this invention include making a cavity between two vertebrae to be fused and implanting a spacer having an open chamber. In some embodiments the chamber is packed with osteogenic material before the spacer is implanted. In other aspects of the invention, osteogenic material is packed into and around the chamber through the mouth or channel after implantation.

[0016] The combination of the open-chambered spacers of this invention with the tools and methods of this invention provide a versatile spacer without any compromise in biomechanical integrity. The spacers can be packed before or after implantation. This invention facilitates implanting a pair of open spacers close to each other in an intervertebral space. Where the spacer is a bone dowel, the dowel can be formed with less bone than is needed for conventional dowels, conserving precious bone stock.

[0017] Accordingly, it is one object of this invention to provide an open-chambered fusion spacer and methods for using the spacer in an arthrodesis procedure.

[0018] Another object is to improve patient incidence of safe and satisfactory spinal stabilization and fusion.

[0019] Another object of this invention is to provide a dowel for vertebral fusions which has improved biomechanical properties and versatility over standard dowels known in the art.

[0020] Still another object of the present invention is to provide a spacer with satisfactory biomechanical features and improved osteogenic and fusion promoting features.

[0021] These and other objects, advantages and features are accomplished according to the spacers, tools and methods of the following description of the preferred embodiments of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022]

Figure 1 shows a standard Cloward Dowel known in the art.
 Figure 2 shows a standard unicortical dowel known in the art.
 Figure 3 shows a diaphysial cortical dowel produced and sold by The University of Florida Tissue Bank, Inc.
 Figure 4 is a side perspective view of one embodiment of the open-chambered spacer of this invention.
 Figure 5 is an end elevational view of the spacer of Figure 4.
 Figure 6 is a top elevational view of a pair of open chambered dowels of this invention implanted within an intervertebral space.
 Figure 7 depicts the anatomy of a lumbar vertebral segment.
 Figure 8 is a top elevational view of a pair of open chambered dowels of this invention implanted within an intervertebral space via an anterior surgical approach.
 Figure 9 is a top elevational view of a pair of open chambered dowels of this invention implanted within an intervertebral space via a posterior surgical approach.
 Figure 10 is a side perspective view of one embodiment of an open chambered dowel having a truncated arm defining a channel to the mouth and chamber.
 Figure 11 is a top perspective view of an open chambered dowel with arms defining concave faces.
 Figure 12 is a top perspective view of an open chambered bone dowel.
 Figure 13 is a side perspective view of one embodiment of this invention in which the dowel is grooved.
 Figure 14 is a side perspective view of a threaded dowel of this invention.
 Figure 15 is a side cross-sectional view of a detail of a portion of the threads of a spacer of this invention.
 Figure 16 shows various cuts across bone diaphysis and the resulting dowels formed according to this invention..
 Figure 17 is a top elevational view of one embodiment of a dowel threader of this invention.
 Figure 18 is a side elevational view of the dowel threader of Figure 17.
 Figure 19 is an end elevational view of the dowel threader of Figures 17 and 18 showing elements of the cutter assembly.
 Figure 20 is a detailed view of a single tooth of one cutter blade of the dowel threader.
 Figure 21 is a global side view of a cutter blade.
 Figure 22 is a detailed side view of the cutter blade of Figure 21.
 Figure 23 is a detailed side view of the cutter blade of Figures 21 and 22.
 Figure 24 is a top perspective view of one embodiment of an insertion tool of this invention.
 Figure 25 is a side perspective view of the tool of Figure 24.
 Figure 26 is a perspective view of a spacer engaging element of an insertion tool.
 Figure 27 is a perspective view of a spacer engaging element of an insertion tool.
 Figure 28 is a side elevational view of an insertion tool engaged to a spacer.
 Figure 29 is a top perspective view of the view shown in Figure 28.
 Figure 30 is an exploded side perspective view of a tool-spacer assembly according to this invention.
 Figure 31 is a side perspective view of a tool-spacer assembly.
 Figure 32 is a top perspective view of a fastener of this invention.
 Figure 33 is a side elevational view of the fastener of Figure 32.
 Figure 34 is a top elevational view of the fastener of Figures 32 and 33.
 Figure 35 is a top elevational view of a spacer according to one specific embodiment of this invention.
 Figure 36 is a side view of the spacer of Figure 35.
 Figure 37 is a front perspective view of the spacer of Figure 35.
 Figure 38 is a detail of a portion of the threaded surface of the spacer of Figure 35.
 Figure 39 is a detail of one embodiment of the thread of one embodiment of the threaded dowel of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0023] For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

[0024] This invention provides spacers having an open-mouthed chamber. These spacers are advantageous for maximum exposure of vertebral tissue to osteogenic material within the chamber and allow close placement of a pair

of spacers within the intervertebral space. The design of these spacers conserve material without compromising bio-mechanical properties of the spacer. This is particularly advantageous when the material is bone because the invention preserves precious allograft. In fact, larger dowels and other shaped grafts can be obtained from smaller bones than was ever thought possible before the present invention. Likewise, smaller dowels having a pre-formed chamber may

5 be efficiently obtained from larger bones.
[0025] Although any open-chambered spacer is contemplated, in one embodiment the spacers are obtained as an off-center transverse plug from the diaphysis of a long bone. This results in a dowel having an open-mouthed chamber. Because the long bone naturally includes the medullary canal, a pre-formed chamber is inherently contained within the dowel. When the plug is cut off-center in a certain way, the dowel includes an open-mouthed chamber. Surprisingly,
 10 the biomechanical properties of these dowels are not compromised by the absence of the missing chamber wall. Referring now to Figures 4 and 5, one embodiment of an interbody fusion spacer of this invention is shown. The spacer 500 includes a body 505 with a tool engagement end 501 and an opposite insertion end 502. The body 505 includes a wall 506 defining a chamber 530 between the two ends 501, 502 and an opening 531 in communication with the chamber 530. Preferably, the insertion end 502 includes a solid protective wall 503 which is positionable to protect the
 15 spinal cord from escape or leakage of osteogenic material from the chamber 530 when the spacer is placed via an anterior approach.

[0026] As shown in Figure 4, the chamber 530 is open in that it also communicates with a further aperture such as a mouth or a channel. The aperture also communicates with the outer surface 510 of the spacer 500, preferably at the tool engagement end 501. The aperture can provide access to the chamber 530 after implantation or can facilitate
 20 insertion of the spacer 530 into the intervertebral space. Comparing Figure 4 with Figure 3, it is evident that the chamber 530 is open so that the body 505 and chamber 530 are substantially C-shaped as opposed to the defined chamber 330 of Figure 3. In some embodiments, including the one depicted in Figure 4, the aperture is a mouth 525 formed by a pair of facing and opposing arms 520, 521.

[0027] Bilateral placement of dowels 500 is preferred as shown in Figure 6. This configuration provides a substantial quantity of bone graft available for the fusion. The dual bilateral cortical dowels 500 result in a significant area of cortical bone for load bearing and long-term incorporation via creeping substitution, while giving substantial area for placement of osteogenic autogenous bone which will facilitate boney bridging across the disc space. The dual dowel placement with facing chambers 530 results in an elongated compartment 540 that can be filled with an osteogenic composition M. This provides for the placement of a significant amount of osteogenic material as well as a large support area of
 25 cortical bone for load bearing.

[0028] The open spacers of this invention are advantageous because they complement the anatomy of the vertebrae V as shown in Figures 7-9. Figure 7 shows the variation in bone strength within the vertebral body V, with weaker bone W, disposed toward the center of the body B, and stronger bone S being disposed around the periphery, closest to the ring apophysis A. The open spacers of this invention are designed to accommodate spinal anatomy. As shown in Figure
 30 8, two open spacers 500' can be implanted with the mouths 525' facing to the center of the intervertebral space. This capitalizes on the load bearing capability of the stronger peripheral bone S of the vertebral body V by placing the structural and load bearing portion of the spacer along the periphery of the body. At the same time, the osteogenic material M placed within the chambers is exposed to the more vascular center area W of the body.

[0029] In a preferred embodiment shown in Figure 10, the first arm 520' or the arm adjacent the tool engagement end 501', is truncated relative to the second arm 521'. This forms a channel 526 from the outer surface 510' to the chamber 530'. Preferably and as shown in Figure 10, the channel 526' is in communication with both the mouth 525' and the chamber 530' although it is contemplated that the channel 526 could be provided in a closed spacer having a chamber and an opening. In some embodiments, such as the spacer 550 depicted in Figure 11, the arms 580, 581 define concave faces or surfaces 582 and 583. The concave faces 582 and 583 are configured to receive a comple-
 35 mentary driving tool.

[0030] The channel 526 of this invention provides important advantages. The channel 526, particularly when formed as a truncated arm 520' as shown in Figure 10, facilitates implantation with an insertion tool. Because the tool can be placed within the channel during implantation, two spacers of this invention can be placed very closely together within the intervertebral space as shown in Figures 6 and 8. The tool need not extend beyond the outer surface of the spacer.
 40 The channel 526 also allows osteogenic material to be packed within the chamber and around the spacer after implantation. A further advantage of the channel is that, when it is formed in combination with the mouth of an open spacer, it allows the chamber of the spacer to be packed before implantation. The tool may be placed within the channel to prevent escape of the osteogenic material from the chamber during implantation. The channel 526 also provides access to the chamber 530' for packing after the spacer 500' is implanted into the disc space.

55 **[0031]** Referring now to Figure 12, in a preferred embodiment, the spacer is a dowel having a longitudinal axis A_1 along a length L of the body 505. The open C-shaped chamber 530 is defined along a second axis A_p substantially perpendicular to the longitudinal axis A_1 . The body 505 has an outer cross-section XS projected on a plane perpendicular to the longitudinal axis A_1 that is substantially uniform along the length L of the body 505.

[0032] The spacers of this invention may be provided with surface features defined in the outer surface 510. Where the spacer is a bone dowel as described herein, the surface features can be machined into the cortical bone. Any desirable surface feature is contemplated. In one embodiment the outer surface 510 of the tool engaging end 501 defines a tool engaging or instrument attachment hole 515 as shown in Figures 4 and 12. In a preferred embodiment, the hole 515 is threaded but any suitable configuration is contemplated. It is sometimes preferable that this end 501 have a generally flat surface to accept the instrument for insertion of the dowel in the recipient.

[0033] In some embodiments, the spacer 500 includes an alignment score mark or groove 516 defined in the tool engagement end 501. In Figure 12 the groove 516 is parallel to the axis A_p of the chamber 530 or perpendicular as shown in Figure 4. The score mark may be widened to form a driver slot for receiving an implantation tool. Alternatively, the end of the dowel may be machined to exhibit a projection instead of a slot. Such a protruding portion of bone may take a straight, flat-sided shape (essentially a mirror image of the slot shown), it may be an elliptical eminence, a bi-concave eminence, a square eminence, or any other protruding shape which provides sufficient end-cap or tool engaging end strength and drive purchase to allow transmission of insertional torque without breaking the dowel or the eminence. In other embodiments, a groove can be omitted to enhance the strength of the tool engaging end 501.

[0034] Other surface features can be defined along the length L of the spacer. The surface features can provide engaging surfaces to facilitate engagement with the vertebrae and prevent slippage of the spacer as is sometimes seen with a smooth graft. Referring now to Figure 13, the spacer 600 includes a groove or stop rib 632 inscribed along the circumference of the spacer. The rib 632 discourages backing out. In other preferred embodiments the outer surface 510' of the dowel 500' defines threads 542 as shown in Figure 14. The initial or starter thread 547 is adjacent the protective wall 503'. As shown more clearly in Figure 15, the threads 542 are preferably uniformly machined threads which include teeth 543 having a crest 544 between a leading flank 545 and an opposite trailing flank 546. Preferably the crest 544 of each tooth 543 is flat. In one specific embodiment, the crest 544 of each tooth 543 has a width w of between about 0.020 inches and about 0.030 inches. The threads 542 preferably define an angle α between the leading flank 545 and the trailing flank 546 of adjacent ones of said teeth 543. The angle α is preferably between about 50 degrees and 70 degrees. Each tooth 543 preferably has a height h' which is about 0.030 inches and about 0.045 inches.

[0035] Machined surfaces, such as threads, provide several advantages that were previously only available with metal implants. Threads allow better control of spacer insertion than can be obtained with a smooth surface. This allows the surgeon to more accurately position the spacer and avoid over-insertion which is extremely important around the critical neurological and vascular structures of the spinal column. Threads and the like also provide increased surface area which facilitates the process of bone healing and creeping substitution for replacement of the donor bone material and fusion. These features also increase postoperative stability of the spacer by engaging the adjacent vertebral end-plates and anchoring the spacer to prevent expulsion. Surface features also stabilize the bone-spacer interface and reduce micromotion to facilitate incorporation and fusion.

[0036] Various configurations of open-chambered spacers are contemplated by this invention. When the spacer is obtained from the diaphysis of a long bone, the shape of the dowel is determined by the location of the cut into the bone shaft. Referring now to Figure 16, by appropriately locating the plug that is cut, "C"-shaped dowels of varying "C"-shaped cavity depths and sidewall thicknesses are achievable. Figure 16A shows the plug that must be cut into the shaft to obtain a diaphysial cortical dowel 300 (see Figure 3) having a sidewall height H1 and a sidewall thickness T1. Figures 16B-16D depict the off-center cuts required to generate "C"-shaped dowels of this invention having different sidewall heights H2-H4 and sidewall thicknesses T2-T4. The sidewall thickness increases from 16A to 16D, even though the diameter of the dowel is unchanged.

[0037] Surprisingly, we have found that the open chambered spacers of this invention have biomechanical properties similar to a spacer having a defined or closed chamber. For example, the open-chambered bone dowel 500' of Figure 14 is no more susceptible to snapping or breakage during machining or implantation than the diaphysial cortical dowel 300 of Figure 3 having a full circular chamber. This strength is retained as long as the thickness T4 of the wall 506' at its narrowest aspect 570 is preferably no less than about 5 mm.

[0038] As any of these open-chambered spacers are implanted and begin to experience axial load, it is expected that the lower the sidewall height H, the greater the load carried by the dowel end 501, 502. However, where the sidewall height H is approximately the same as the dowel diameter D, the sidewall 506 may carry a greater share of this axial load.

[0039] In some embodiments, the wall 506 may include upper and lower flattened portions to stabilize the dowel by neutralizing any rotational torque that may be induced by pressure on the sidewall. This could be achieved by reducing the height H of the sidewall 505 and ends 501, 502 by filing or like means. These considerations may be less important for a threaded dowel than a non-threaded dowel as the threads tend to "bite" into the bone in which they are implanted, thereby preventing any rotation.

[0040] For cervical fusions, the dowel is preferably obtained from the fibula, radius, ulna or humerus. The dimensions of such dowels are typically between about 8-15mm in length or depth and about 10-14mm in diameter. For thoracic and lumbar fusions, the dowel is preferably obtained from the humerus, femur or tibia. The dimensions of such dowels

are typically between about 10-30mm in length and about 14-20mm in diameter.

[0041] The chamber may be packed with any suitable osteogenic material. In a preferred embodiment, the osteogenic composition M has a length which is greater than the length of the chamber 530 so that the osteogenic composition will contact the endplates of the adjacent vertebrae when the spacer 500 is implanted within the vertebrae. This provides better contact of the composition with the endplates to stimulate bone ingrowth.

[0042] Any suitable osteogenic material or composition is contemplated, including autograft, allograft, xenograft, demineralized bone, synthetic and natural bone graft substitutes, such as bioceramics and polymers, and osteoinductive factors. The terms osteogenic material or osteogenic composition used here means virtually any material that promotes bone growth or healing including autograft, allograft, xenograft, bone graft substitutes and natural, synthetic and recombinant proteins, hormones and the like.

[0043] Autograft can be harvested from locations such as the iliac crest using drills, gouges, curettes and trephines and other tools and methods which are well known to surgeons in this field. Preferably, autograft is harvested from the iliac crest with a minimally invasive donor surgery. The osteogenic material may also include bone reamed away by the surgeon while preparing the end plates for the spacer.

[0044] Advantageously, where autograft is chosen as the osteogenic material, only a very small amount of bone material is needed to pack the chamber. The autograft itself is not required to provide structural support as this is provided by the spacer. The donor surgery for such a small amount of bone is less invasive and better tolerated by the patient. There is usually little need for muscle dissection in obtaining such small amounts of bone. The present invention therefore eliminates or minimizes many of the disadvantages of employing autograft.

[0045] Natural and synthetic graft substitutes which replace the structure or function of bone are also contemplated for the osteogenic composition. Any such graft substitute is contemplated, including for example, demineralized bone matrix, mineral compositions and bioceramics. As is evident from a review of An Introduction to Bioceramics, edited by Larry L. Hench and June Wilson (World Scientific Publishing Co. Ptd. Ltd, 1993, volume 1), there is a vast array of bioceramic materials, including BIOGLASS®, hydroxyapatite and calcium phosphate compositions known in the art which can be used to advantage for this purpose. That disclosure is herein incorporated by reference for this purpose. Preferred calcium compositions include bioactive glasses, tricalcium phosphates and hydroxyapatites. In one embodiment, the graft substitute is a biphasic calcium phosphate ceramic including tricalcium phosphate and hydroxyapatite.

[0046] In some embodiments, the osteogenic compositions used in this invention comprise a therapeutically effective amount to stimulate or induce bone growth of a substantially pure bone inductive or growth factor or protein in a pharmaceutically acceptable carrier. The preferred osteoinductive factors are the recombinant human bone morphogenetic proteins (rhBMPs) because they are available in unlimited supply and do not transmit infectious diseases. Most preferably, the bone morphogenetic protein is a rhBMP-2, rhBMP-4 or heterodimers thereof.

[0047] Recombinant BMP-2 can be used at a concentration of about 0.4 mg/ml to about 1.5 mg/ml, preferably near 1.5 mg/ml. However, any bone morphogenetic protein is contemplated including bone morphogenetic proteins designated as BMP-1 through BMP-13. BMPs are available from Genetics Institute, Inc., Cambridge, Massachusetts and may also be prepared by one skilled in the art as described in U.S. Patent Nos. 5,187,076 to Wozney et al.; 5,366,875 to Wozney et al.; 4,877,864 to Wang et al.; 5,108,922 to Wang et al.; 5,116,738 to Wang et al.; 5,013,649 to Wang et al.; 5,106,748 to Wozney et al.; and PCT Patent Nos. WO93/00432 to Wozney et al.; WO94/26893 to Celeste et al.; and WO94/26892 to Celeste et al. All osteoinductive factors are contemplated whether obtained as above or isolated from bone. Methods for isolating bone morphogenetic protein from bone are described in U.S. Patent No. 4,294,753 to Urist and Urist et al., 81 PNAS 371, 1984.

[0048] The choice of carrier material for the osteogenic composition is based on biocompatibility, biodegradability, mechanical properties and interface properties as well as the structure of the load bearing member. The particular application of the compositions of the invention will define the appropriate formulation. Potential carriers include calcium sulphates, polylactic acids, polyanhydrides, collagen, calcium phosphates, polymeric acrylic esters and demineralized bone. The carrier may be any suitable carrier capable of delivering the proteins. Most preferably, the carrier is capable of being eventually resorbed into the body. One preferred carrier is an absorbable collagen sponge marketed by Integra LifeSciences Corporation under the trade name Helistat® Absorbable Collagen Hemostatic Agent. Another preferred carrier is a biphasic calcium phosphate ceramic. Ceramic blocks are commercially available from Sofamor Danek Group, B. P. 4-62180 Rang-du-Fliers, France and Bioland, 132 Rou d Espangne, 31100 Toulouse, France. The osteoinductive factor is introduced into the carrier in any suitable manner. For example, the carrier may be soaked in a solution containing the factor.

[0049] The present invention also provides methods for making the open spacers of this invention. In one embodiment, a method for making an open chambered bone dowel includes obtaining an off-center plug from the diaphysis of a long bone so that the dowel has an open chamber. The open chamber is preferably substantially concave or C-shaped and has an axis that is substantially perpendicular to the long axis of the dowel. Appropriate human source bones include the femur, tibia, fibula, humerus, radius and ulna. Long bones from other species are also contemplated although human source bones are generally preferred for human recipients.

[0050] The first step is to identify an acceptable donor based upon appropriate standards for the particular donor and recipient. For example, where the donor is human, some form of consent such as a donor card or written consent from the next of kin is required. Where the recipient is human, the donor must be screened for a wide variety of communicable diseases and pathogens, including human immunodeficiency virus, cytomegalovirus, hepatitis B, hepatitis C and several other pathogens. These tests may be conducted by any of a number of means conventional in the art, including but not limited to ELISA assays, PCR assays, or hemagglutination. Such testing follows the requirements of: (i) American Association of Tissue Banks, Technical Manual for Tissue Banking, Technical Manual - Musculoskeletal Tissues, pages M19-M20; (ii) The Food and Drug Administration, Interim Rule, Federal Register/Vol. 58, No. 238/Tuesday, December 14, 1994/Rules and Regulations/65517, D. Infectious Disease Testing and Donor Screening; (iii) MMWR/Vol. 43/No. RR-8m Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and organs, pages 4-7; (iv) Florida Administrative Weekly, Vol. 10, No. 34, August 21, 1992, 59A-1.001-01459A-1.005(12)(c), F.A.C., (12)(a)-(h), 59A-1.005 (15), F.A.C., (4)(a)-(8). In addition to a battery of standard biomechanical assays, the donor, or their next of kin, is interviewed to ascertain whether the donor engaged in any of a number of high risk behaviors such as having multiple sexual partners, suffering from hemophilia, engaging in intravenous drug use, etc. Once a donor has been ascertained to be acceptable, the bones useful for obtention of the dowels are recovered and cleaned.

[0051] Preferably, the bone plugs are obtained using a diamond or hard metal tipped cutting bit which is water cleaned and cooled. Commercially available bits (e.g. core drills) having a generally circular nature and an internal vacant diameter between about 10mm to about 20 mm are amenable to use for obtention of these bone plugs. Such core drills are available, for example, from Starlite, Inc. In one embodiment, a pneumatic driven miniature lathe having a spring loaded carriage which travels parallel to the cutter is used. The lathe has a drive system which is a pneumatic motor with a valve controller which allows a desired RPM to be set. The carriage rides on two runners which are 1.0 inch stainless rods and has travel distance of approximately 8.0 inches. One runner has set pin holes on the running rod which will stop the carriage from moving when the set pin is placed into the desired hole. The carriage is moveable from side to side with a knob which has graduations for positioning the graft. A vice on the carriage clamps the graft and holds it in place while the dowel is being cut. The vice has a cut-out area in the jaws to allow clearance for the cutter.

[0052] In operation, the carriage is manually pulled back and locked in place with a set pin. The graft is loaded into the vice and is aligned with the cutter. Sterile water is used to cool and remove debris from graft and/or dowel as the dowel is being cut. The water travels down through the center of the cutter to irrigate as well as clean the dowel under pressure. After the dowel is cut, sterile water is used to eject the dowel out of the cutter.

[0053] Dowels of any size can be prepared according to this invention. In some embodiments, the dowels range from 5mm to 30mm diameters with lengths of about 8mm to about 36mm being generally acceptable, although other appropriate gradations in length and diameter are available. For cervical dowels, such as anterior cervical fusion or ACF dowels, lengths of 8mm, 9mm, up to about 15mm are generally desirable. Dowels of differing diameter are most conveniently obtained as follows:

Diameter	Source
10.6-11mm	fibula
12mm	radius
14mm	ulna
14+mm	small humeri

[0054] Dowels for thoracic and lumbar fusions, such as anterior thoracic inner body fusion (ATIF) and anterior lumbar inner body fusion (ALIF) dowels, respectively, having a depth of between about 10 - 36 mm, and preferably between about 15-24mm, are generally acceptable, depending on the needs of a particular patient. Dowels of differing diameter for thoracic and lumbar fusions are most conveniently obtained as follows:

Diameter	Source
14-16mm	humerus
16-18mm	femur
18-20mm	tibia

While the foregoing diameters and source bones for such dowels is a useful guide, one of the significant advances provided by this invention is that the open-chambered dowel of this invention provides tremendous flexibility with respect to the source bone used.

[0055] Since the spacers of the preferred embodiment are obtained from off-center transverse plugs across the

diaphysis of long bones, each dowel has the feature of having a substantially "C"-shaped chamber through the dowel perpendicular to the length of the dowel formed by the intersection of the natural intramedullary canal of the source bone and the cutter blade as it forms the plug. The canal cavity in the long bone is, in vivo, filled with bone marrow. In the standard Cloward Dowel and unicortical dowels known in the art, no such natural cavity exists and the cancellous bone that forms the body of such dowels tends to be too brittle to accept machining of such a cavity. The dowels of this invention, by the nature of their origin, inherently define such a cavity. Naturally, based on this disclosure, those skilled in the art will recognize that other bone sources could be used which do not have the intramedullary canal, and if sufficient strength is inherent to the bone, a cavity or chamber could be machined. In addition, it will be appreciated from the instant disclosure that an existing diaphysial cortical dowel (Figure 3), available from the University of Florida Tissue Bank, Inc., could be modified by machining one side of such a dowel until one wall of the dowel is sufficiently abraded to "break-through", thereby transforming the diaphysial cortical dowel into the "C"-shaped dowel of this invention. Accordingly, such extensions of this invention should be considered as variants of the invention disclosed herein and therefore come within the scope of the claims appended hereto.

[0056] The marrow is preferably removed from the intramedullary canal of the diaphysial plugs and the cavity is cleaned, leaving the chamber. The spacer may be provided to the surgeon with the chamber prepacked or empty for the surgeon to pack during surgery. The cavity or chamber can then be packed with an osteogenic material or composition.

[0057] The plug is then machined, preferably in a class 10 clean room to the dimensions desired. The machining is preferably conducted on a lathe such as a jeweler's lathe, or machining tools may be specifically designed and adapted for this purpose. Specific tolerances for the dowels and reproducibility of the product dimensions are important features for the successful use of such dowels in the clinical setting.

[0058] In some embodiments, the forward end of the dowel which is to be inserted into a cavity formed between adjacent vertebrae is chamfered. The curvature of the chamfered end facilitates insertion of the dowel into the intervertebral space. Chamfering can be accomplished by appropriate means such as by machining, filing, sanding or other abrasive means. The tolerance for the chamfering is fairly liberal and the desired object is merely to round or slightly point the end of the dowel that is to be inserted into the cavity formed between adjacent vertebrae to be fused.

[0059] In some embodiments, the invention includes methods for providing surface features into the walls of the dowels. The methods may include defining a tool or instrument attachment hole in an end of the dowel. The hole may be drilled and preferably tapped. Preferably, the dowel will be of such dimensions as to fit standard insertion tools, such as those produced by Sofamor Danek Group, Inc. (1800 Pyramid Place, Memphis, TN 38132, (800) 933-2635). In addition, a score mark or driver slot may be inscribed on the instrument attachment end of the dowel so that the surgeon can align the dowel so that the chamber is parallel with the length of the recipient's spinal column. The mark or slot allows the surgeon to orient the dowel properly after the dowel is inserted and the chamber is no longer visible. In the proper orientation, the endplates of the adjacent vertebrae are exposed to osteogenic material in the chamber. In some embodiments, the driver slot is omitted to preserve as much bone stock, and therefore strength, in the end as possible.

[0060] Surface features such as grooves and threads may be preferably defined or inscribed on the outer cylindrical surface of the dowel. Machining of such features on dowels known in the art is difficult if not impossible due to the brittle cancellous nature of such dowels. Accordingly, the dowels of this invention have the advantage of having very good biomechanical properties amenable to such machining.

[0061] Those skilled in the art will also recognize that any of a number of different means may be employed to produce the threaded or grooved embodiments of the dowel of this invention. However, one preferred embodiment of a thread cutter 400 is depicted in Figures 17-23. The cutter 400 includes a drive shaft 402 for supporting a spacer and a cutter assembly 420. The terminal end 406 of the drive shaft 402 includes a spacer engager 407. In one embodiment and as best shown in Figure 18, the spacer engager 407 is a protruding element which matingly corresponds to the driver slot on the tool end of the open-chambered spacers of this invention. The drive shaft 402 can be turned to rotate and advance the spacer incrementally through the cutter assembly 420 to inscribe a feature such as a thread into the surface of the spacer.

[0062] In one embodiment, the drive shaft 402 can be turned by a handle 401 rigidly attached to a first end 402a of the shaft 402. The drive shaft 402 preferably is provided with a graduated segment means for controlled incremental advancement of the drive shaft 402 upon rotation of the handle 401. In this embodiment, the means is a threaded portion 403. Support means 404 and 405 are preferably provided for alignment and support of the shaft 402. Each of the support means 404, 405 include a wall 404a, 405a defining an aperture 404b, 405b. The support means 404, 405 may have controlling means within the apertures 404b, 405b for controlling rotation and incremental advancement of the shaft. In some embodiments, the controlling means include matching threads or bearings.

[0063] The thread cutter assembly includes a housing 408 and blades 421, 422 and guide plates 424, 425 mounted within the housing 408. The cutter blades 421, 422 are held in place in the housing 408 by fixation wedges 423a and 423b while guide plates 424 and 425, having no cutting teeth, are held in place by fixation wedges 423c and 423d.

Fixation wedges 423a-d are held in place by screws 426a-d. The foregoing arrangement is preferred, as it allows for easy assembly and disassembly of the cutter assembly, removal of the cutter blades, cleaning of the various components, and if desired, sterilization by autoclaving, chemical, irradiative, or like means. The cutter blades 421, 422 and guide plates 424, 425 may be rigidly fixed in place by increasing the tension created by tightening screws 426a-d, which draws the fixation wedges 423a-d into the housing 408, thereby clamping these elements in place. Naturally, based on this disclosure, those skilled in the art will be able to develop equivalents of the cutter assembly system described herein, such as by use of wing-nuts, welding or like means to affix these various elements in appropriate cutting relationship to each other.

[0064] Fixation wings 421c and 421d are provided to allow proper seating of the cutter blade upon insertion into the housing 408. At θ a line is provided on cutter blades 421 and 422, which allows for appropriate registration between cutter blades 421 and 422 during manufacture thereof. Upon insertion into the housing 408, it is critical that the blades and the teeth thereon are appropriately registered so that as blade 421 cuts into the bone dowel as it is rotationally advanced through the cutter assembly 420, blade 422 is appropriately situated so that its matching teeth are in phase with the thread inscribed by the teeth on blade 421. This is accomplished by a combination of the fixation wings 421d and 421c properly seating in the housing 408 such that wall 421c abuts the housing 408 and the housing 408 walls about the insides of wings 421d and 421c.

[0065] The cutting edges 421a, 422a of the blades 421, 422 are disposed in relation to each other so that they are on axis. The cutting edges 421a, 422a and the guiding edges 424a, 425a of the guide plates define an aperture 427 for a spacer or dowel. The diameter of the dowel that may be threaded according to this device is defined by the diameter of the aperture 427.

[0066] The supports 404 and 405 and the housing 408 for the cutter assembly are all preferably mounted on a steady, solid, weighty base unit 409 via screws, welding, or like attachment means at 410a-f. The supports and the cutter assembly are configured so that there is an appropriate travel distance 411 from the fully backed out terminal end of the drive shaft 406 to the end of the cutter assembly 420. This distance must be sufficient to allow insertion of a dowel blank and advancement of the blank through the cutter assembly 420 to allow a fully threaded dowel to emerge from the cutter assembly.

[0067] The cutter maintains true tooth form from top to bottom, so that the cutter can be sharpened by surface grinding the face. This is achieved by wire-cutting the teeth such that there is about a 5° incline 62c between the descending vertices at the front and rear of each tooth, and about an 8° incline 62d between the front and rear of the top of each tooth. This aspect can best be seen in Figure 20. Also, the thickness of the cutter blade, 62c, preferably about 0.100" can be seen in that figure. The angle 61 in Figure 20 is preferably about 60° . The width of the top of the tooth 62b is preferably about 0.025". The pitch 60 is preferably about 0.100". Figure 21 shows an overall view of the cutter blades 421 or 422 which are assembled in the cutter assembly housing 408. The entire length of the cutter blade 421b is about 1.650".

[0068] Details of the blades 421, 422 are shown in Figures 22 and 23. In this embodiment, the cutter blade 421 has twelve cutting teeth 431-442. The cutting edge 422a has eleven teeth 451-461 spread over the length of the blade 422. At 451, the first tooth at 0.004" in this example is encountered by the blank and at each successive tooth, an increase of about 0.004" is made until the final tooth height of about 0.039 is reached at 460 and 461. As a dowel blank is fed into the cutter assembly, it first encounters a truncated tooth at 431, and at every subsequent tooth, the height of the tooth is reached, in this example, of 0.039" at 441 and 442. The truncated teeth 431-440 feed into the dowel being cut along the 30° line so that the teeth cut on only two sides. The dotted line 443 shows the final pitch and form that the cutter will cut in the bone dowel.

[0069] It will be recognized by those skilled in the art that all of the foregoing elements should preferably be manufactured from durable materials such as 440 stainless steel, or like materials. In particular, the cutting surfaces 421a and 422a of the blades 421 and 422 are made from hard metal.

[0070] In operation, based on the foregoing description, it will be appreciated that the cutter blades 421 and 422 are placed into the housing 408, clamped into place via the fixation wedges 423 a, b and the screws 426 a, b after the blades have been properly seated and the two blades are perfectly aligned. A blank dowel is then loaded into the orifice 427 and the drive shaft with the protruding element 408 is inserted into a drive slot a dowel. As the handle 401 is turned, the drive shaft forces the dowel to rotate and advance incrementally through the cutter assembly 420, thereby inscribing the thread defined by the cutter blades 421 and 422 into the outer cylindrical surface or circumference of the dowel.

[0071] As noted above, those skilled in the art will recognize that modifications to the specifics of the device described will allow for the preparation of the varied threads or grooves in the circumference of the dowel. For example, to form a groove in a dowel, the dowel could be mounted in a lathe, such as those known in the art and commercially available, for example from SHERLINE PRODUCTS, INC., SAN MARCOS, CALIFORNIA 92069, and a cutter blade applied as the dowel is rotated.

[0072] The final machined product may be stored, frozen or freeze-dried and vacuum sealed as known in the art for later use.

[0073] The spacers of this invention may be conveniently implanted with known instruments and tools. Any instrument which will firmly hold the implant and permit the implant to be inserted is contemplated. Preferably, the instrument will be adapted to compensate for the open structure of the spacers of this invention.

[0074] The present invention further contemplates insertion devices for facilitating the implantation of spacers, implants or bone graft. The tools include spacer engaging means for engaging a spacer or other item and occlusion means for blocking an opening defined in the spacer. One embodiment of an insertion tool of this invention is depicted in Figures 24-26.

[0075] In one embodiment, an insertion tool 800 is provided which includes a housing 805 having a proximal end 806 and an opposite distal end 807 and defining a passageway 810 between the two ends. A shaft 815 which has a first end 816 and an opposite second end 817 is disposed within the passageway 810. The first end 816 of the shaft 815 is adjacent the distal end 807 of the housing 805. The first end 816 defines a spacer engager 819. An occlusion member 820 is attached to the housing 805.

[0076] The spacer engager 819 has any configuration which will engage a spacer. In some embodiments the spacer engager 819 includes a post 818 as shown in FIG. 26 for engaging a hole in the spacer. The post 818 may have any configuration which will provide for mating engagement with a hole in a spacer. For example, in preferred embodiments, the engager 819 is threaded as shown in Figure 26 to matingly engage a threaded tool hole. Other embodiments include sharply pointed tip 819 as shown in Figure 24 or a hexagonal shaped tip 819" (Figure 27). In each case, the engager is shaped and sized to mate engagingly with the tool hole of the spacer. In other embodiments, the spacer engaging means is a pair of prongs having opposite facing spacer engaging members for grasping an outer surface of the spacer.

[0077] The spacer insertion tool 800 also includes an occlusion member 820 for blocking an opening defined in the spacer when the spacer engager 819 is engaged to the spacer. In a preferred embodiment, the occlusion member 820 is extendable from the distal end 807 of the housing 805 for blocking an opening in the spacer. As shown in Figure 28, the occlusion member 820 closes the mouth 525' and channel 526 defined in the spacer 500'.

[0078] The occlusion member 820 is preferably slideably engaged to the housing 805. Referring now to Figure 29, in one embodiment, the occlusion member 820 includes a plate 821 which defines a groove 822. A fastener 830 is engaged to a fastener bore 809 in the housing 805 and the groove 822 is disposed around the fastener 830. In this way, the plate 821 is slideable relative to the housing 805.

[0079] As shown in Figure 30, the housing 805 is preferably provided with a recess 808 which is defined to accept the occlusion member 820 without increasing the effective diameter of the device 800. The occlusion member is also adapted for the best fit with the spacer. For example, the interior surface 824 of the occlusion member would be curved to complement the scalloped faces 582 and 583 shown in Figure 11 for crescent engagement. Referring now to Figures 30 and 31, the plate 821 of the occlusion member 820 preferably includes a curved superior surface 825 which approximates and completes the minor diameter of the dowel 500' when the spacer engager 819 is engaged to the tool engaging hole 515' and the occlusion member 820 is blocking the channel 526 of the spacer 500'. Preferably, the plate 821 and the arm 520' of the spacer 500' will be configured such that the plate 821 will not extend beyond the channel 526 when the tool 800 is engaged to the spacer 500'. In other words, the curved superior surface 825 will not increase the effective root diameter RD of the the threaded outer surface 510'. This facilitates rotation and screw insertion of the spacer and occlusion member combination into an intervertebral space.

[0080] The tool 800 depicted in Figure 24 also includes a handle portion 840. The handle portion includes means for slidably moving the shaft 815 within the housing 805 and for rotating the post 818. In the embodiment shown in Figures 24 and 25 the means includes a thumbwheel 841. In some embodiments, the handle portion 840 has a Hudson end attachment 842.

[0081] Referring now to Figures 32-34, the fastener 830 is preferably provided with a housing engaging means shown in Figure 32 as a post 834, and a plate engaging means or head portion 835. The fastener 830 preferably includes an internal hex 837 for receiving a fastener driving tool. The post portion 834 may be threaded for mating engagement with threaded bore 809 in the housing 805. In preferred embodiments shown in Figures 29 and 30, the plate 821 defines a recess 826 surrounding the groove 822. The diameter d1 of the head portion 835 is greater than the diameter d2 of the post 834. The diameter d2 is less than the width w1 of the groove 822. The diameter d1 of the head portion is greater than width w1 but preferably no greater than the distance w2 between the outer edges 827 of the recess 826. Thus, the head portion 835 of the fastener 830 can rest on the recess 826 while the post portion 834 extends through the groove 822. In this way, plate 821 is slidable relative to the housing 805. This also provides for a low profile device which can be inserted into various cannula for percutaneous procedures.

[0082] The spacers and tools in this invention can be conveniently incorporated into known surgical, preferably minimally invasive, procedures. The spacers of this invention can be inserted using laparoscopic technology as described in Sofamor Danek USA's Laparoscopic Bone Dowel Surgical Technique, © 1995, 1800 Pyramid Place, Memphis, Tennessee 38132, 1-800-933-2635, preferably in combination with the insertion tool 800 of this invention. Spacers of this invention can be conveniently incorporated into Sofamor Danek's laparoscopic bone dowel system that facilitates an-

terior interbody fusions with an approach that is much less surgically morbid than the standard open anterior retroperitoneal approaches. This system includes templates, trephines, dilators, reamers, ports and other devices required for laparoscopic dowel insertion. Alternatively, a minimally invasive open anterior approach using Sofamor Danek's open anterior bone dowel instrumentation or a posterior surgical approach using Sofamor Danek's posterior approach bone dowel instrumentation are contemplated.

[0083] The present invention also includes methods for fusing adjacent vertebrae. The spine may be approached from any direction indicated by the circumstances. The vertebrae and the intervertebral space are prepared according to conventional procedures to receive the spacer. A spacer of the appropriate dimensions is selected by the surgeon, based on the size of the cavity created and the needs of the particular patient undergoing the fusion. The spacer is mounted on an instrument, preferably via an instrument attachment hole. In one embodiment, an osteogenic material is placed within the chamber of the spacer and the channel and or mouth of the spacer is then blocked with an occlusion member of the instrument. The spacer is then inserted into the cavity created between the adjacent vertebra to be fused. The spacer is oriented within the intervertebral space so the osteogenic material in the chamber is in communication with the end plates of the vertebra. Once the spacer is properly oriented within the intervertebral space, the occlusion member of the instrument can be withdrawn from the spacer aperture and the spacer engager is disengaged from the spacer.

[0084] In some embodiments, osteogenic material is packed into the chamber through the channel after implantation. In still other embodiments, a second spacer is implanted into the intervertebral space. Figure 8 depicts placement of two dowels of this invention implanted from an anterior approach, while Figure 9 shows bilateral placement of dowels from a posterior approach. In each case the channel 526 opens adjacent the tool engaging end 501' allowing access to the chamber 530' from either the anterior or posterior approach.

[0085] The combination of spacers of this invention with the tools of this invention allow the spacers to provide the benefits of an open spacer without suffering any biomechanical disadvantage or increased fiddle factor. The occlusion member 825 blocks the mouth or channel to lessen the stress on the wall of the spacer for smooth insertion. The occlusion member also allows the chamber to be packed with osteogenic material before the spacers are implanted. Once the spacer is implanted and the occlusion member is withdrawn, additional osteogenic material can be packed into the chamber or around the spacers. In some procedures two open spacers are packed with the mouths facing one another as depicted in Figure 8. The open mouth of the spacers along with the tools of this invention allow the spacers to be packed closely together because virtually no clearance is required for the insertion tool. The open mouth also allows the chambers to be packed after the spacer is implanted. This is greatly enhanced when one of the arms is truncated, leaving a channel from outside the disc space to the chamber as shown in Figure 10.

[0086] It has been found that certain dimensions are preferred when a spacer of this invention is a bone dowel. For the substantially "C"-shaped chamber, 530, a regular or irregular hole having a diameter no greater than about 0.551" (14mm) is preferred with a minimum wall thickness 570 at the root of the thread of preferably no less than about 5mm. Those skilled in the art will recognize that the foregoing specifics, while preferable, may be modified depending on the particular surgical requirement of a given application.

[0087] In another specific embodiment, depicted in Figures 35-38, the diameter D1 of the dowel is 18mm and the length L1 is 36mm. In this specific embodiment, the length L2 of the solid side is shorter than the length of the open side L1 due to the natural curve of the bone. The shorter length L2 is preferably at least 30% of the longer length L1. The length of the truncated arm is preferably between about 50-85% of the diameter of the dowel D1. In this embodiment, the insertion end of the dowel includes a flattened portion F1. The length of the flattened portion F1 is preferably at least 70% of the diameter of the dowel D1. As best shown in Figure 36, the depth E1a, E1b, E2a, E2b of the end-caps or insertion end and tool engaging ends of the dowel are preferably at least about 3mm. The depth of the bevel B2 of the threads is preferably 1mm while the bevel angle B1 is preferably about 45 degrees. The depth of the drive slot C2 is preferably about 1.5mm deep and the width C1 is about 5.5mm. The diameter D2 of the tapped instrument attachment hole is about 3.3 mm with T5 indicating the tapped thread.

[0088] Various surface feature configurations are contemplated by this invention. Referring now to Figure 38, a detail of the thread of one embodiment is provided. The thread pitch T1 is about 2.5 mm. The length T2 of the top of each tooth of the thread is about 0.6mm, the depth T4 of the thread is about 1mm and the width T3 of the thread at the thread root is about 0.8mm. The outer thread angle A3 is about 60 degrees in this embodiment. Figure 39 shows a detail of a portion of a threaded dowel of another embodiment which has ten right handed threads per inch at a helix angle at the root diameter of about 2.8892°. In this specific embodiment, the pitch T1' is 0.100"; the thread angle-A1' is 60°; the thread crest width T2' is 0.025"; the thread height T4' is 0.039"; and the radius of the various thread angle as it changes R is typically about 0.010".

[0089] While the foregoing description discloses specific aspects of this invention, those skilled in the art will recognize that any of a number of variations on the basic theme disclosed herein can be made. It is contemplated that the spacers of this invention can be formed of any suitable biocompatible material, including metals, ceramics, polymers, composites, alloys and the like. Some embodiments include titanium, stainless steel, and Hedrocel®. Thus, for exam-

ple, differing shapes can be made from the diaphysis of various bones and could be used for other orthopaedic purposes than vertebral fusions. In addition, any of a number of known bone treatments can be applied to the dowel of this invention to alter its properties. For example, the methods disclosed in U.S. Patent Nos. 4,627,853; 5,053,049; 5,306,303 and 5,171,279 can be adapted and applied to the invention disclosed herein. Accordingly the disclosures of those patents is herein incorporated by reference for this purpose.

[0090] Having described the dowel of this invention, its mode of manufacture and use, the following specific examples are provided by way of further exemplification and should not be interpreted as limiting on the scope of the invention herein disclosed and claimed.

EXAMPLES

Example-1 Torsional Testing of "C"-shaped Dowel

[0091] The C-shaped dowel of this invention was tested and the following measurements made of the dowel's ability to withstand insertional torque. The data presented here are for the 16 mm dowel. However, similar results are expected for other lengths of the dowel of this invention. For each dowel, a measured torque is applied to the dowel as it is maintained in a stationary position. For biological insertion of dowels, torques no higher than about 1 newton-meter are expected. The various dimensions measured in the following table correspond to the dimension shown in Figures 35-38:

Sample	Diam. (mm) D1	OD (mm) W1	ID (mm) W1*	Height (mm) H**	Calc. Thickness***	% diff. Mcas. -Calc.	Failure Torque	Failure Type
1	15.8	5.1	4.6	13.2	4.0	15	4.00	s. wall
2	15.8	5.5	4.8	13.2	4.0	19	3.5	s. wall
3	15.9	6.2	5.3	13.4	4.3	25	3.89	slot
4	15.9	7	6.3	14.1	5.1	23	4.95	slot
5	15.6	5.8	5.4	13.6	4.5	21	5.2	s. wall
6	15.8	5.5	4.9	13.1	4.0	24	436	s. wall
7	15.7	5.8	5.4	13.4	4.3	27	4.00	slot
W1*=W1-T4; H**=see H1-H4, Figure 16; calc. thickness***=theoretical calculations based on sidewall height, H								

[0092] From these data, it is clear that dowels of this invention are able to withstand considerably more than the 1 newton-meter of torque required to insert the dowel in physiological situations. From theoretical calculations based on the sidewall height, the difference between the calculated sidewall thickness and the measured thickness was found to be, on average, about 22%, leading to the conclusion that only approximately 22% the measured thickness is cancellous bone, and the substantial majority of the bone is cortical bone.

Example 2-Compression Testing:

[0093] The "C"-shaped dowel of this invention was compressively tested and the load to failure was measured. It is anticipated that loads no higher than about 10,000 newtons are likely to be experienced in-place in the vertebral column. Compression testing of several different "C"-shaped dowels of this invention indicated that dowels of this invention survive axial compression loads significantly higher than the 15,000 newton threshold:

#	Thread	Avg D1	L1	E2a	E2b	Avg E2	E1a	E1b	Avg E1	mass g	Failure Load (N)
1	no	15.9	25.5	5.3	4.7	5.0	3.9	4.4	4.2	4.193	4372
2	yes	15.9	23.7	5.1	5.1	5.1	4.2	5.0	4.6	4.073	13502
3	no	15.9	23.7	4.8	5.3	5.1	3.8	2.6	3.3	4.035	13748
4	yes	15.9	22.5	7.1	7.0	7.1	7.0	5.4	6.2	5.075	20940
5	poor	16.0	23.4	5.6	5.4	5.5	5.8	6.2	6.0	4.986	22420
6	yes	15.7	26.1	7.1	7.1	7.1	8.4	8.6	8.5	5.331	24500
7	yes	16.8	23.8	5.4	5.0	5.2	6.0	6.0	6.0	3.928	14389
8	yes	17.6	22.4	4.8	5.5	5.2	5.8	4.6	5.2	5.448	16730
9	poor	16.9	22.2	6.7	5.2	8.0	6.4	4.7	5.1	5.220	19576
10	poor	17.9	28.3	7.8	7.2	7.5	7.6	7.2	7.4	6.201	20606
11	yes	17.9	21.2	4.9	6.8	5.9	4.5	4.4	4.5	5.654	21461
12	yes	17.8	23.6	6.6	6.3	6.5	6.0	5.4	5.7	5.706	23971
13	yes	19.9	25.6	6.3	6.6	6.5	6.4	6.4	6.4	7.915	24761

[0094] The mean load to failure of these dowels is 18544 newtons, indicating that on average, more dowels can withstand 15000 newtons axial pressure than not. These data also indicate the need for diligent quality control to eliminate dowels that do not withstand minimal axial compression loads from being implanted.

Example 3-Cervical Fusion Using "C"-shaped Dowel

[0095] Preoperative Diagnosis. Ruptured cervical disc and spondylosis C5-6.

[0096] Operative Procedure. Anterior cervical discectomy and fusion C5-6.

[0097] After satisfactory general endotracheal anesthesia in the supine position, the patient is prepped and draped in the routine fusion. Incision is made in the skin length of the neck and carried through the platysma muscle. Dissection is carried down to expose the anterior vertebral column and the appropriate space identified by x-ray. Discectomy and foraminotomy are then performed and there is found a central, extruded fragment of disc toward the right side. When adequate decompression is achieved, a "C"-shaped dowel is cut from bone bank fibular and counter-sunk between the vertebral bodies to afford distraction. The wound is then irrigated with Bacitracin and closed in layers with Dexon and sterile strips.

[0098] Postoperative evaluation and subsequent patient monitoring reveals successful operative outcome and good vertebral fusion.

[0099] It should be understood that the example and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and the scope of the appended claims.

Claims

1. An interbody fusion spacer, comprising:

an elongate body defining a longitudinal axis and having a chamber therein;

a first arm extending from the body transverse to the longitudinal axis; and

an opposite second arm also extending from the body transverse to the longitudinal axis, the first arm and said second arm forming a mouth to said chamber, wherein the first arm is truncated relative to the second arm.

2. The spacer of claim 1 wherein the body comprises a tool engaging end having a tool engaging hole therein for receiving a driving tool for implanting the spacer.
3. The spacer of claim 2 wherein the body comprises a slot surrounding said tool engaging hole.
4. The spacer of any of claim 1-3 wherein the body comprises an outer surface defining bone engaging features.
5. The spacer of claim 4 wherein the bone engaging features include one or more of: threads, grooves and ribs.
6. The spacer of any of claims 1-5 wherein the chamber is C-shaped.
7. The spacer of claim 6 wherein the chamber is derived from the medullary canal.
8. The spacer of any of claims 1-7 wherein the spacer comprises cortical bone.
9. The spacer of any of claims 1-8 further comprising an osteogenic material packed within said chamber.
10. The spacer of claim 9 wherein said osteogenic material comprises autogenous bone, bone morphogenetic protein, a calcium phosphate composition or a mixture of these.
11. The spacer of any of claims 1-10 wherein the body defines a round dowel.
12. The spacer of any of claims 1-11 wherein the body comprises flattened upper and lower surfaces.
13. The spacer of claim 12 wherein the body comprises an outer surface defining bone engaging features.
14. The spacer of any of claims 1-13 wherein the body has a chamfered insertion end.
15. The spacer of any of claims 1-14 having a length of between about 8mm to about 36mm.
16. The spacer of any of claims 1-15 having a diameter of between about 10mm and about 24mm.
17. A hollow intervertebral spacer, comprising:
 - an elongated body having an outer surface and a longitudinal axis along a length of said body and defining a chamber therethrough along a second axis substantially perpendicular to said longitudinal axis;
 - a first arm connected to said body;
 - an opposite second arm connected to said body and facing said first arm; and
 - said first arm and said second arm forming a mouth to said chamber.
18. The spacer of claim 17 wherein said body further comprises:
 - a tool engaging end defining a tool engaging hole for receiving a driving tool for implanting the spacer.
19. The spacer of claim 18 wherein said anterior surface further defines a slot surrounding said tool engaging hole.
20. The spacer of claim 17 wherein said outer surface defines threaded bone engaging portions.
21. The spacer of claim 17 wherein said wall is curved and said chamber is substantially C-shaped.
22. The spacer of claim 17 wherein said body is composed of a porous material.
23. The spacer of claim 17 wherein said body is composed substantially of cortical bone.
24. The spacer of claim 17 wherein said first arm is truncated relative to said second arm.
25. The spacer of claim 19 wherein said outer surface defines threaded bone engaging portions and said body is composed of cortical bone.

26. The spacer of claim 20 wherein said spacer is a bone dowel obtained from the diaphysis of a long bone having a medullary canal, said chamber including a portion of the canal.

27. The spacer of claim 17, further comprising an osteogenic material packed within said chamber.

28. The spacer of claim 27 wherein said osteogenic material comprises autograft, allograft, xenograft, demineralized bone, a calcium phosphate material, a bioceramic, bioglass, an osteoinductive factor or mixtures of thereof.

29. An interbody fusion spacer, comprising:

a body having a wall defining a chamber, the body defining an opening in communication with said chamber, said wall having a first arm and an opposite second arm facing said first arm, said first arm and said second arm forming a mouth to said chamber, wherein said first arm is truncated relative to said second arm.

30. The spacer of claim 29 wherein said body further comprises:

a tool engaging end defining a tool engaging hole for receiving a driving tool for implanting the spacer.

31. The spacer of claim 30 wherein said anterior surface further defines a slot surrounding said tool engaging hole.

32. The spacer of claim 29 wherein said body further comprises:

an outer surface defining threaded bone engaging surfaces.

33. The spacer of claim 29 wherein said wall is curved and said chamber is C-shaped.

34. The spacer of claim 29 wherein said spacer comprises cortical bone.

35. The spacer of claim 29 further comprising an osteogenic material packed within said chamber.

36. A graft comprising an elongated body consisting essentially of cortical bone, said body having an outer surface and a longitudinal axis along a length of said body and defining a chamber therethrough along a second axis substantially perpendicular to said longitudinal axis, said body further defining a channel defined along said longitudinal axis and in communication with said chamber and said outer surface.

37. The graft of claim 36 wherein said outer surface defines threaded bone engaging surfaces.

38. The graft of claim 36 further comprising an osteogenic material packed within said chamber.

39. A hollow intervertebral spacer, comprising:

a cylindrical body having a wall, said wall having an outer surface and defining a chamber and an opening in communication with said chamber; and a channel defined in said wall in communication with said chamber and said outer surface.

40. The spacer of claim 29 wherein said outer surface defines threaded bone engaging portions.

41. A bone graft having a C-shaped wall defining a chamber.

42. The spacer of claim 41 wherein said graft is a bone dowel obtained from the diaphysis of a long bone having a medullary canal, said chamber including a portion of the canal.

43. A "C"-shaped dowel substantially composed of cortical bone.

44. The "C"-shaped dowel of claim 43 comprising a bone plug obtained from the diaphysis of a long bone, said dowel having a substantially "C"-shaped chamber.

45. The "C"-shaped dowel of claim 44 having a chamfered insertion end.

46. The "C"-shaped dowel of claim 44 further comprising a tool engaging end defining an instrument attachment hole.
47. The "C"-shaped dowel of claim 46 wherein the tool engaging end also defines a driver slot surrounding said hole.
- 5 48. The "C"-shaped dowel of claim 44 further comprising an external feature machined into an outer surface of the dowel.
49. The "C"-shaped dowel of claim 48 wherein said feature includes a groove.
- 10 50. The "C"-shaped dowel of claim 48 wherein said feature includes threads formed along a portion of the length of the dowel.
51. The "C"-shaped dowel of claim 43 having a length of between about 8mm to about 36mm.
- 15 52. The "C"-shaped dowel of claim 51 having a diameter of between about 10mm and about 24mm.
53. The "C"-shaped dowel of claim 44 further comprising an osteogenic composition packed within said chamber.
- 20 54. The "C"-shaped dowel of claim 53 wherein said osteogenic composition comprises autogenous bone, bone morphogenetic protein, a calcium phosphate composition or a mixture of these.
55. The "C"-shaped dowel of claim 43 obtained as an off-center transverse plug from the shaft of a donor's fibula, radius, ulna, humerus, femur or tibia.
- 25 56. A method of making a dowel which comprises machining an off-center transverse plug from the diaphysis of a donor's fibula, radius, ulna, humerus, femur or tibia, said plug having a diameter of between about 10mm and about 24mm and a depth (length) of between about 8mm and about 30mm such that the resulting dowel has, running through it, perpendicular to the long axis of the dowel, a substantially "C"-shaped chamber.
- 30 57. The method of claim 56 further comprising chamfering one end of said plug to form a generally curved surface for ease of insertion of the dowel into an intervertebral cavity.
58. The method of claim 56 further comprising machining an instrument attachment hole into one end of the dowel.
- 35 59. The "C"-shaped dowel of claim 43 prepared by a process comprising machining an off-center transverse plug from the diaphysis of a donor's fibula, radius, ulna, humerus, femur or tibia, said plug having a diameter of between about 10mm and about 24mm and a length of between 8mm and about 36mm such that the resulting dowel has, running through it, perpendicular to the long axis of the dowel, a substantially "C"-shaped chamber.
- 40 60. The "C"-shaped dowel of claim 43 having an outer surface defining a surface feature .
61. The "C"-shaped dowel of claim 60 wherein said feature includes a groove.
62. The "C"-shaped dowel of claim 60 wherein said feature includes threads formed along a portion of the length of
45 the dowel.
63. The "C"-shaped dowel of claim 62 wherein said thread has a pitch of about 0.1".
- 50 64. A spacer insertion tool, comprising:
a housing having a proximal end and an opposite distal end and defining a passageway between said proximal end and said distal end;
a shaft having a first end and an opposite second end, said shaft disposed within said passageway with said first end adjacent said distal end, said first end defining a spacer engager; and
55 an occlusion member extendable from said distal end of said housing for blocking an opening defined in the spacer when said spacer engager is engaged to the spacer.
65. The tool of claim 64, further comprising a fastener attached to said shaft and wherein said occlusion member

includes a plate defining a groove, said groove disposed around said fastener so that said plate is slidable relative to said housing.

5 66. The tool of claim 65 wherein said plate has a curved superior surface which approximates the outer surface of the spacer when said spacer engaging means is engaged to the spacer and said occlusion means is blocking the opening of the spacer.

67. The tool of claim 64 wherein said shaft is slidably disposed within said passageway.

10 68. The tool of claim 64 wherein said spacer engager is threaded for mating engagement with a threaded hole in a spacer.

69. The tool of claim 64 wherein said spacer engager is a hex for mating engagement with an internal hex in a spacer.

15 70. An insertion tool for inserting a spacer into an intervertebral space, comprising:

spacer engaging means for engaging the spacer; and
occlusion means separate from said spacer engaging means for blocking an opening defined in the spacer.

20 71. The tool of claim 70 wherein said occlusion means includes a plate, said plate having a curved superior surface which approximates the outer surface of the spacer when said spacer engaging means is engaged to the spacer and said occlusion means is blocking the opening of the spacer.

25 72. The tool of claim 70 wherein said spacer engaging means includes a post for engaging a hole in the spacer.

73. The tool of claim 72 wherein said post is threaded for mating engagement with a threaded hole in a spacer.

74. The tool of claim 72 wherein said post is a hex for mating engagement with an internal hex in a spacer.

30 75. The tool of claim 70 wherein said spacer engaging means is a pair of prongs having opposite, facing spacer engaging members for grasping an outer surface of the spacer.

35 76. A driving tool for implanting an interbody spacer in a space between adjacent vertebrae, the spacer including a body defining a chamber and an opening in communication with the chamber, the body having a pair of arms facing one another and forming a mouth to the chamber, and an anterior surface defining a tool engaging hole, the tool comprising:

spacer engaging means for engaging the tool engaging hole; and
occlusion means for blocking said mouth.

40 77. The tool of claim 76 further comprising a housing and wherein said occlusion means is extendable from said housing.

45 78. The tool of claim 76 wherein said spacer engaging means is a threaded post for threading engagement with the tool engaging hole.

79. A method for fusing two adjacent vertebrae, comprising the steps of:

50 providing a spacer, the spacer including a body having a wall, said wall having an outer surface and defining a chamber and an opening in communication with said chamber, and a channel defined in said wall in communication with said chamber and said outer surface;
preparing the vertebrae and the intervertebral space between the vertebrae to receive the spacer;
placing the spacer into the intervertebral space after the preparing step so that the opening is in communication with at least one of the vertebrae; and
55 packing osteogenic material into the channel after the placing step.

80. A method for fusing two adjacent vertebrae, comprising the steps of:

providing a spacer, the spacer including a body having a wall, said wall having an outer surface and defining a chamber and an opening in communication with said chamber, and a channel defined in said wall in communication with said chamber and said outer surface;
 preparing the vertebrae and the intervertebral space between the vertebrae to receive the spacer;
 5 packing osteogenic material into the chamber;
 blocking the channel; and
 placing the spacer into the intervertebral space after the blocking step so that the opening is in communication with at least one of the vertebrae.

10 **81.** The method of claim 80 further comprising:

implanting a second spacer into the intervertebral space after the placing step, the second spacer having a body having a wall, said wall having an outer surface and defining a chamber and an opening in communication with said chamber, and a channel defined in said wall in communication with said chamber and said outer surface;
 15 surface; and
 orienting the first spacer and the second spacer so that the channels of the first and second spacers face one another.

20 **82.** The method of claim 81 further comprising packing an osteogenic material into the channels of the first and second spacers.

83. The method of claim 80,

further comprising providing a tool of claim 27; engaging the spacer engager of the tool to the spacer; and
 25 wherein the blocking step includes extending the occlusion member to block the channel.

30 **84.** The spacer of claim 17 wherein said body is composed of a metal, a ceramic, a polymer or a composite or alloy thereof.

85. The spacer of claim 29 wherein said body is composed of a metal, a ceramic, a polymer or a composite or alloy thereof.

35 **86.** The spacer of claim 17 wherein said outer surface includes a curved portion and a flattened portion.

87. The spacer of claim 29 wherein said body further comprises an outer surface that defines a curved portion and a flattened portion.

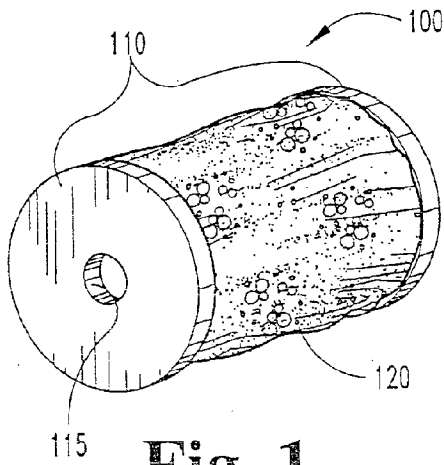


Fig. 1
(Prior Art)

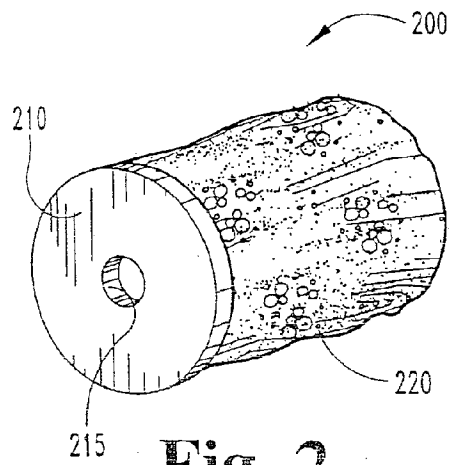


Fig. 2
(Prior Art)

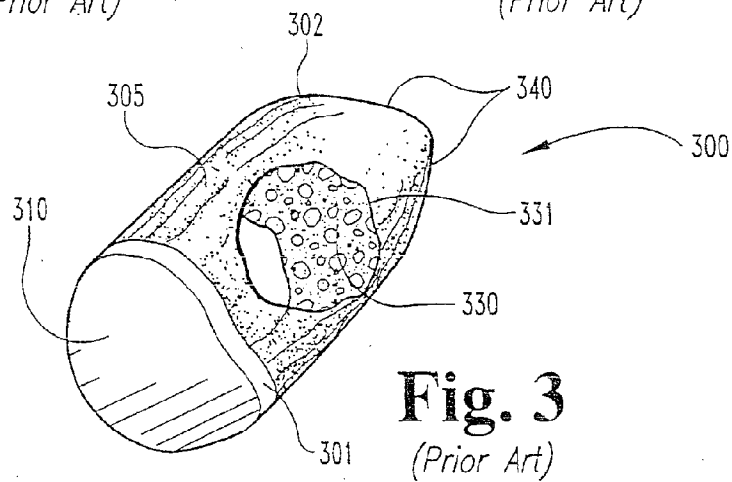


Fig. 3
(Prior Art)

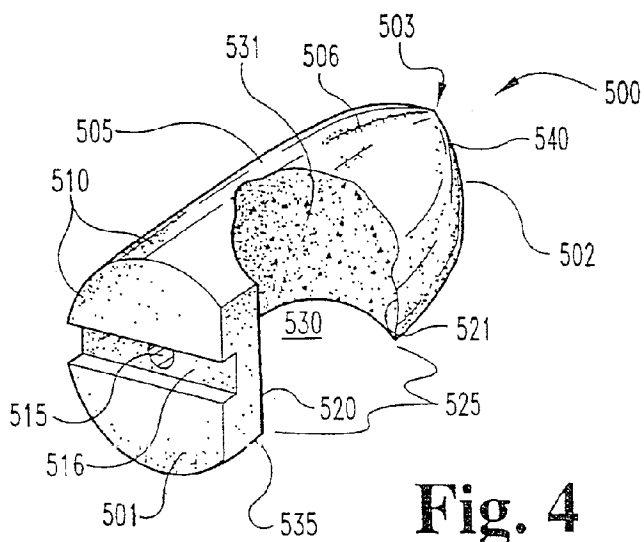


Fig. 4

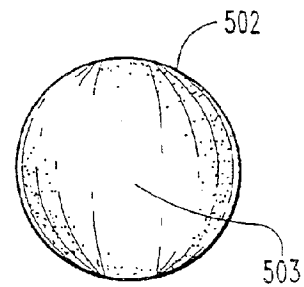


Fig. 5

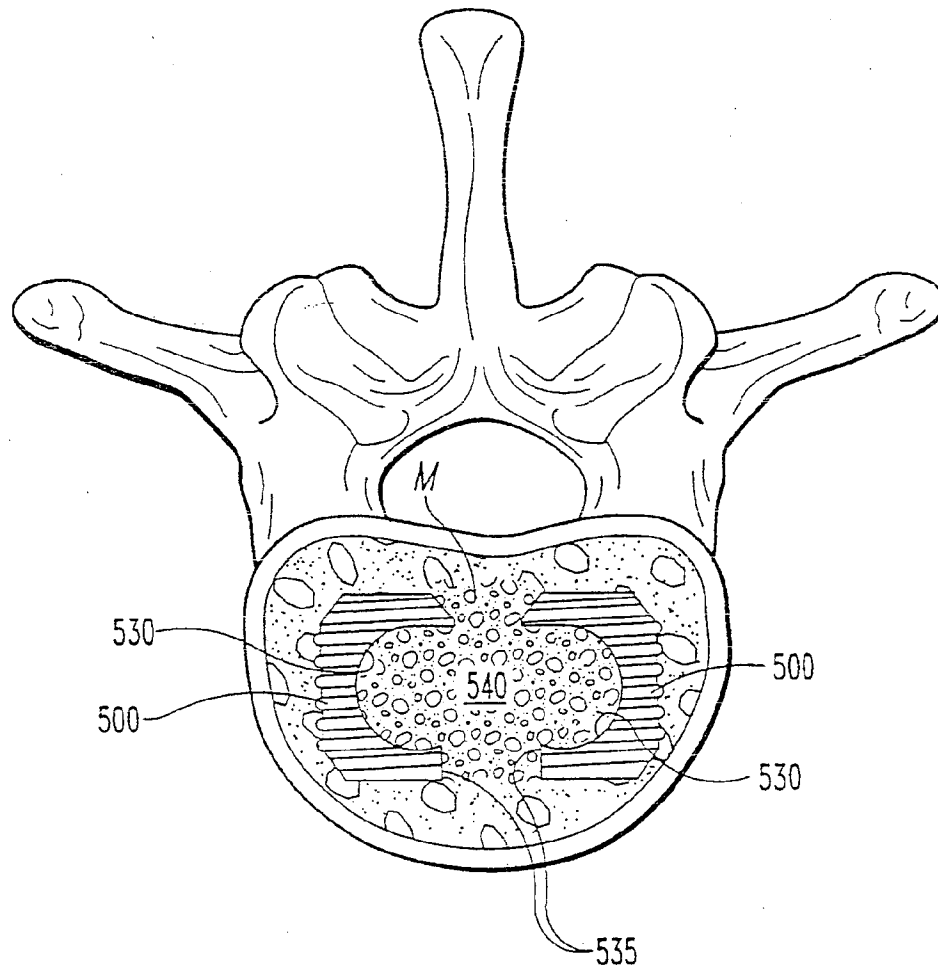
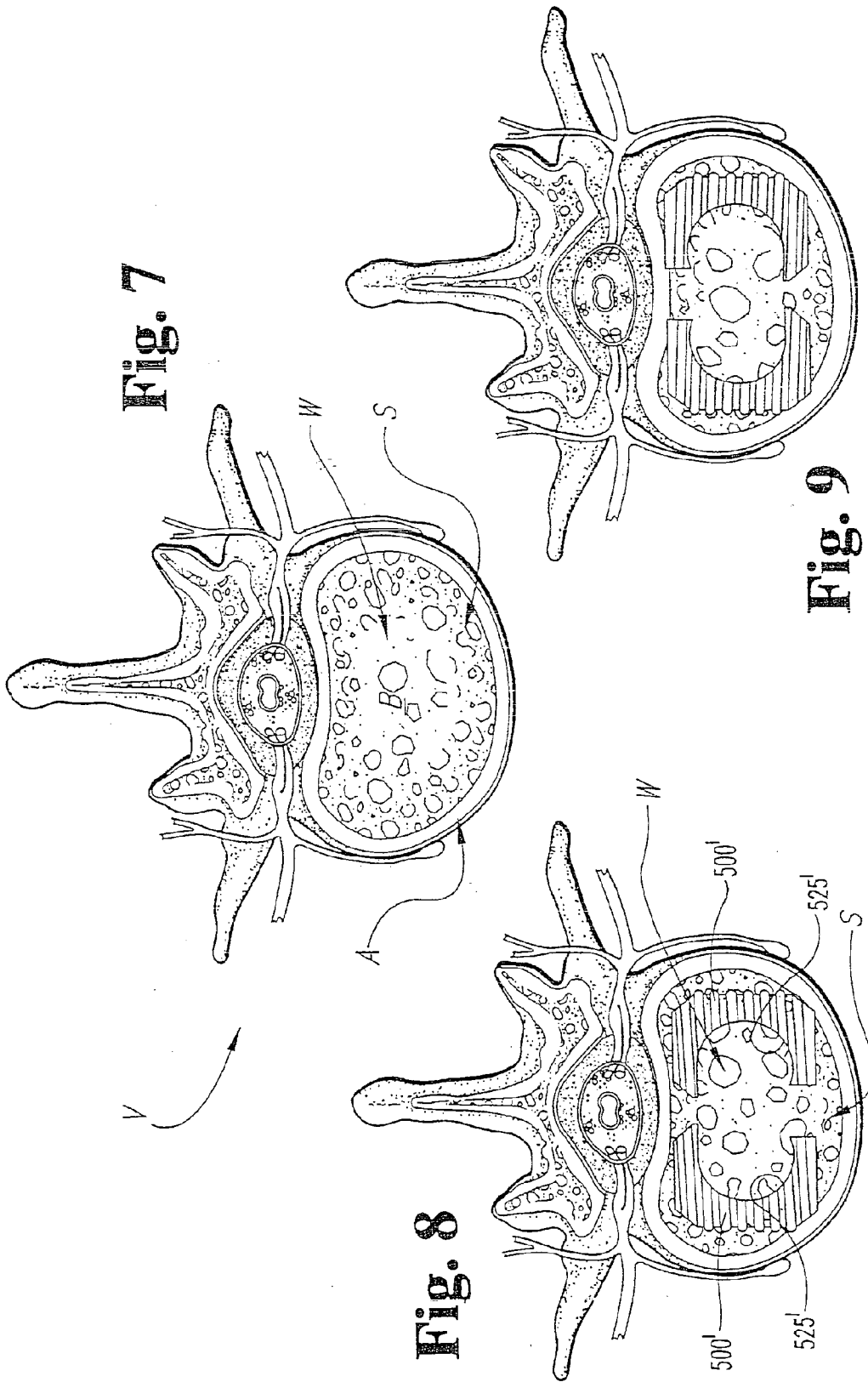


Fig. 6



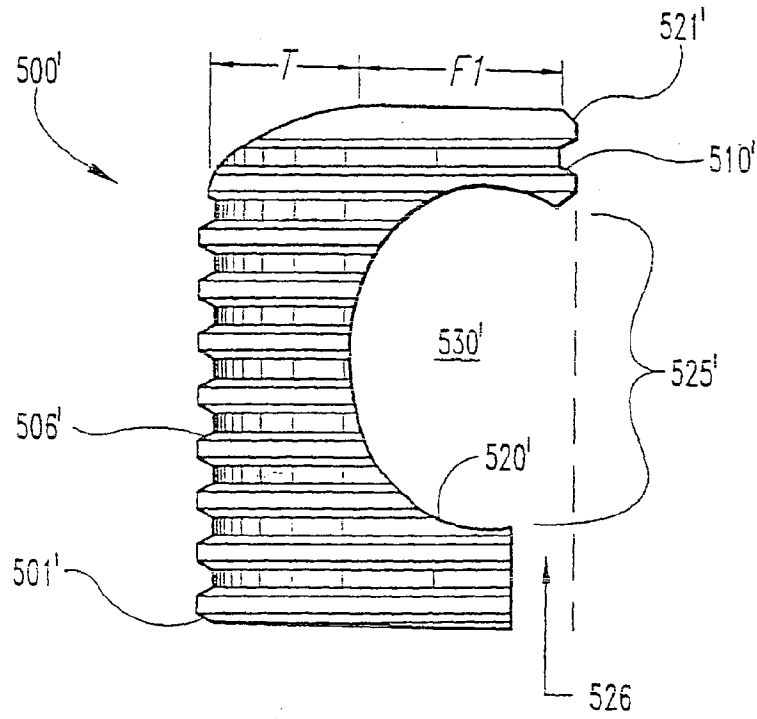


Fig. 10

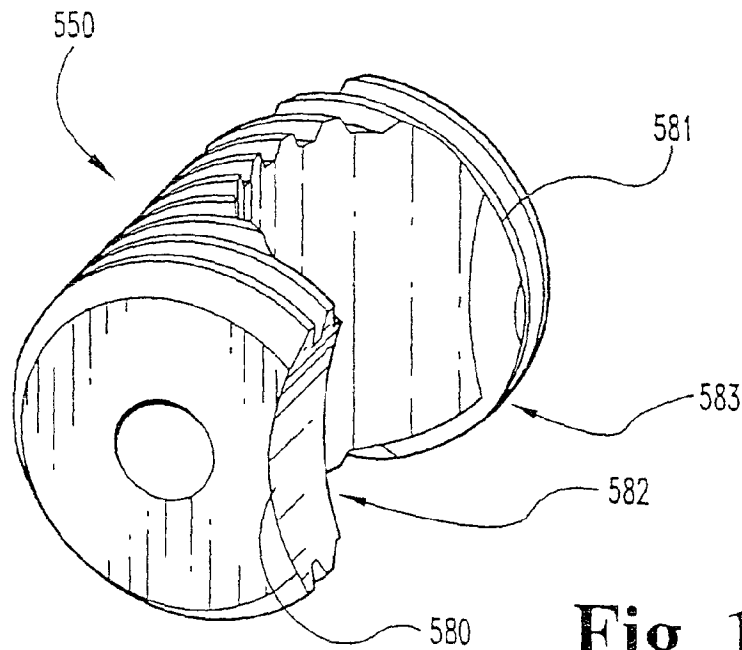


Fig. 11

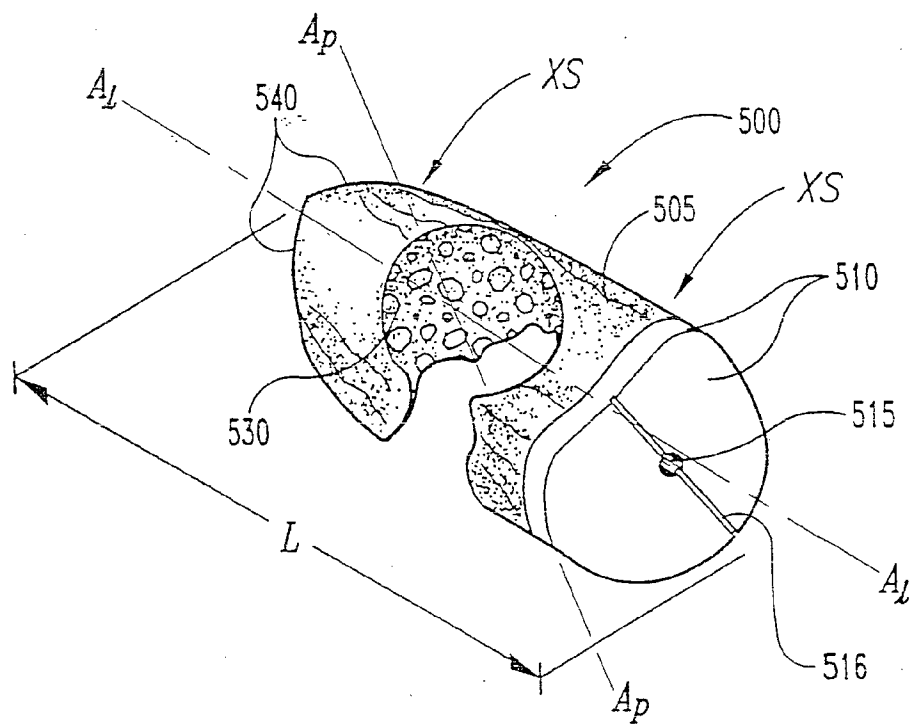


Fig. 12

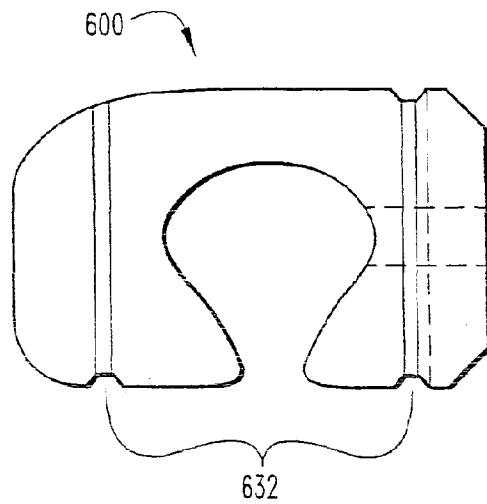


Fig. 13

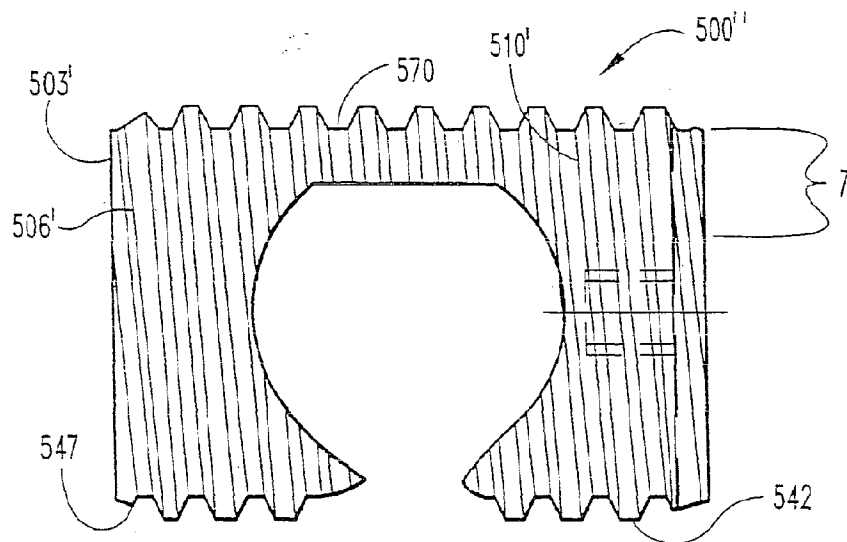


Fig. 14

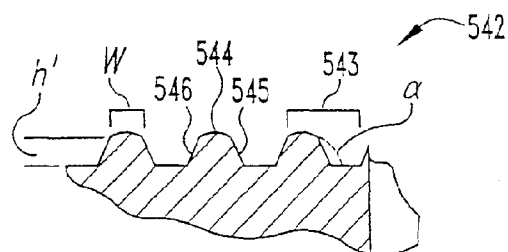


Fig. 15

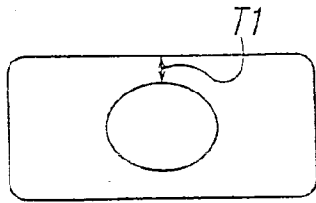


Fig. 16A

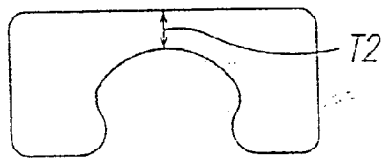


Fig. 16B

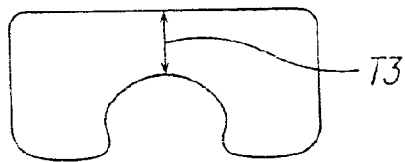


Fig. 16C

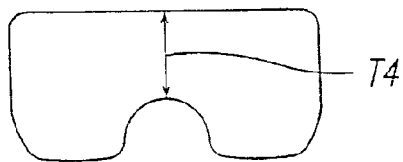


Fig. 16D

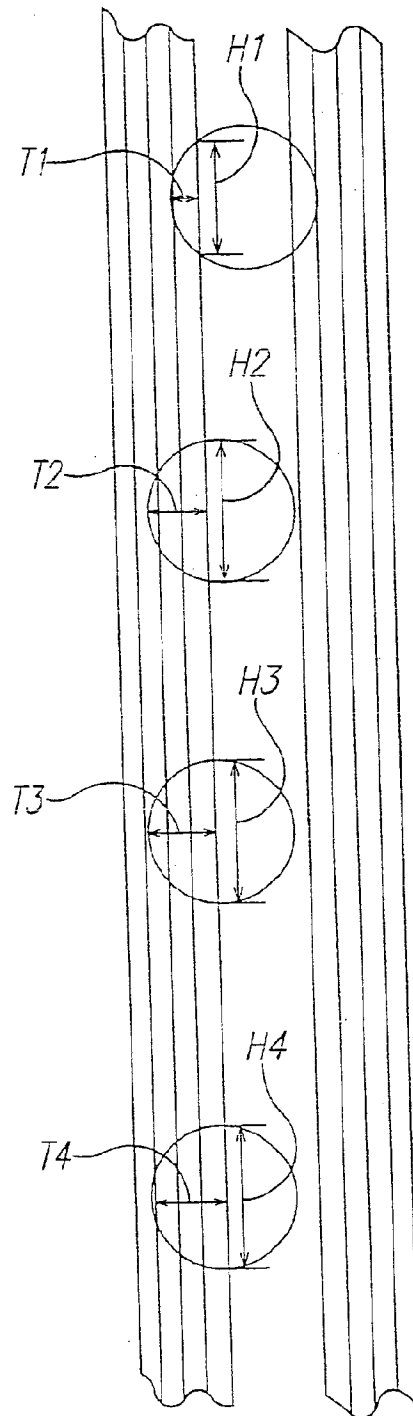


Fig. 16

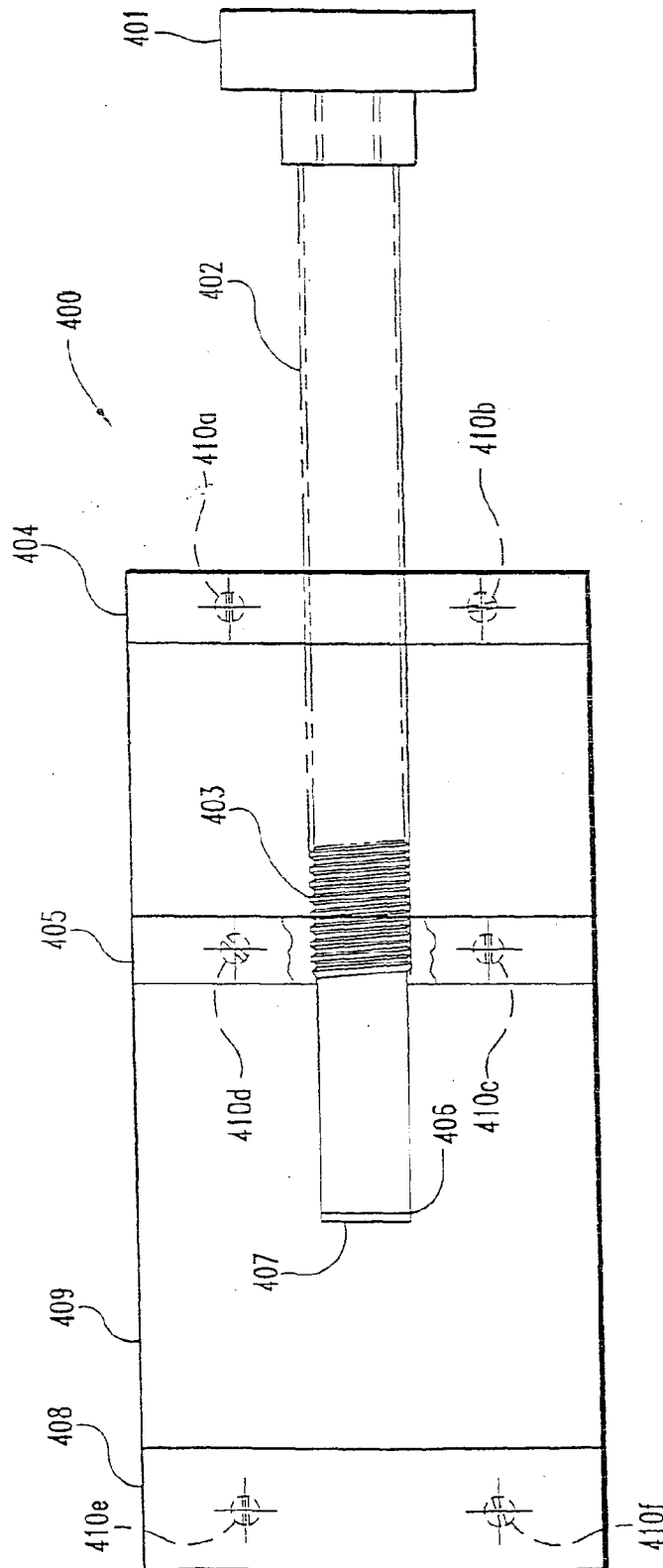


Fig. 17

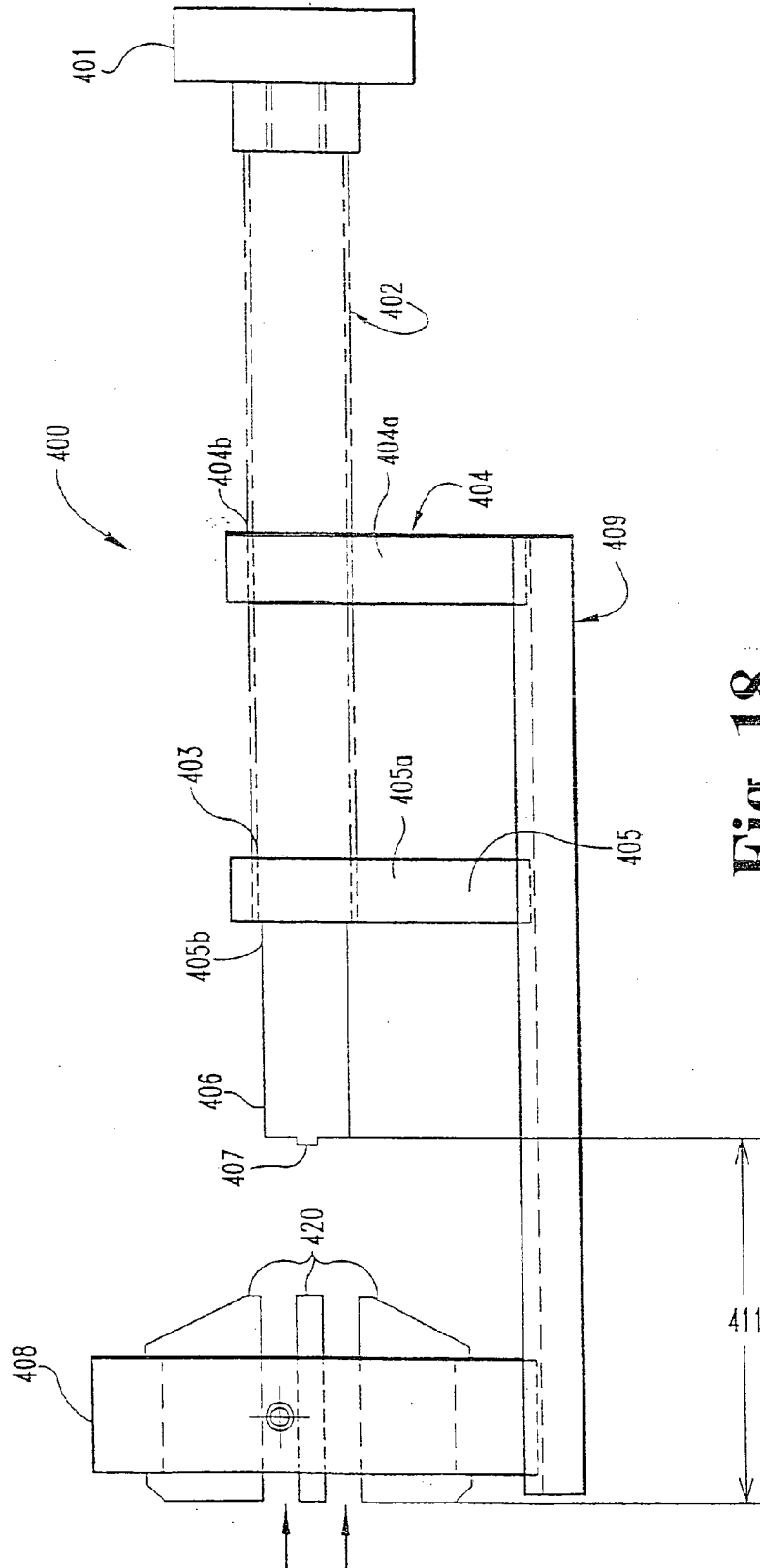


Fig. 18

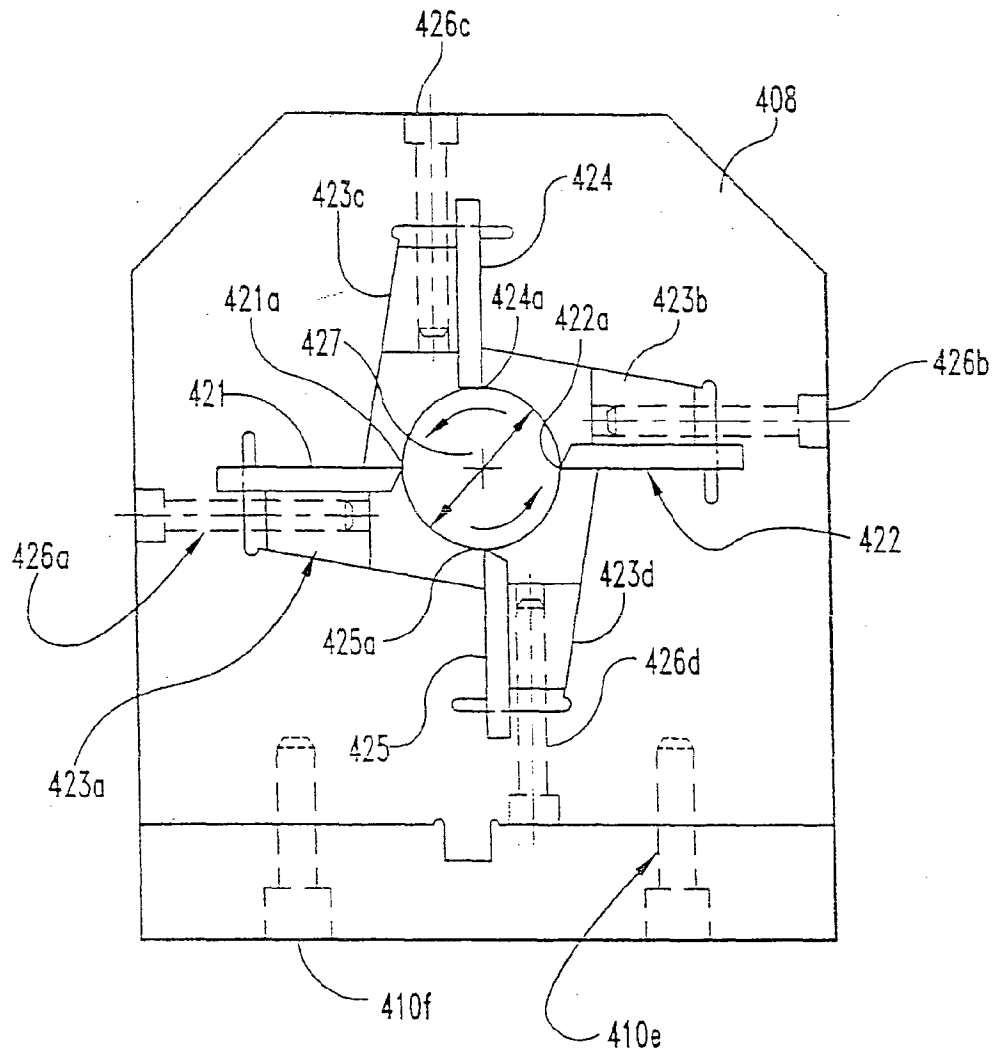


Fig. 19

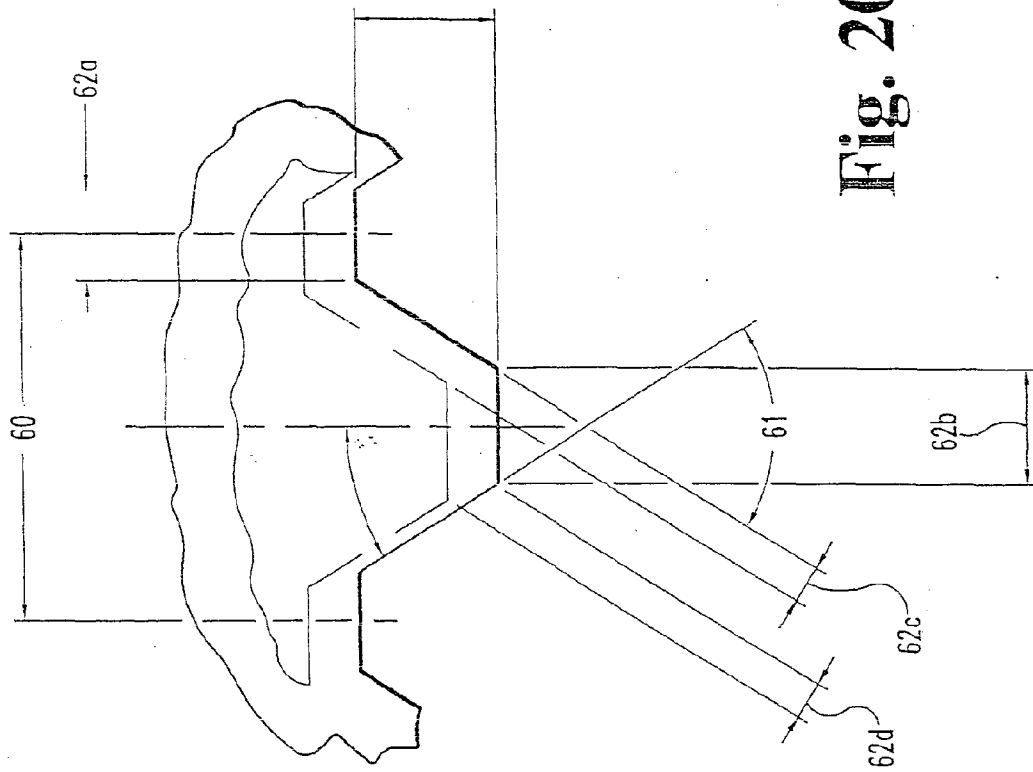


Fig. 20

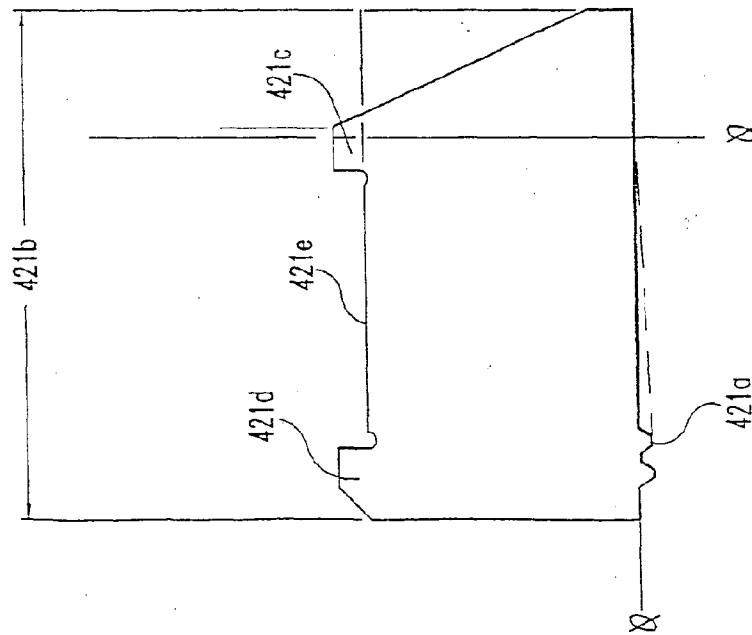


Fig. 21

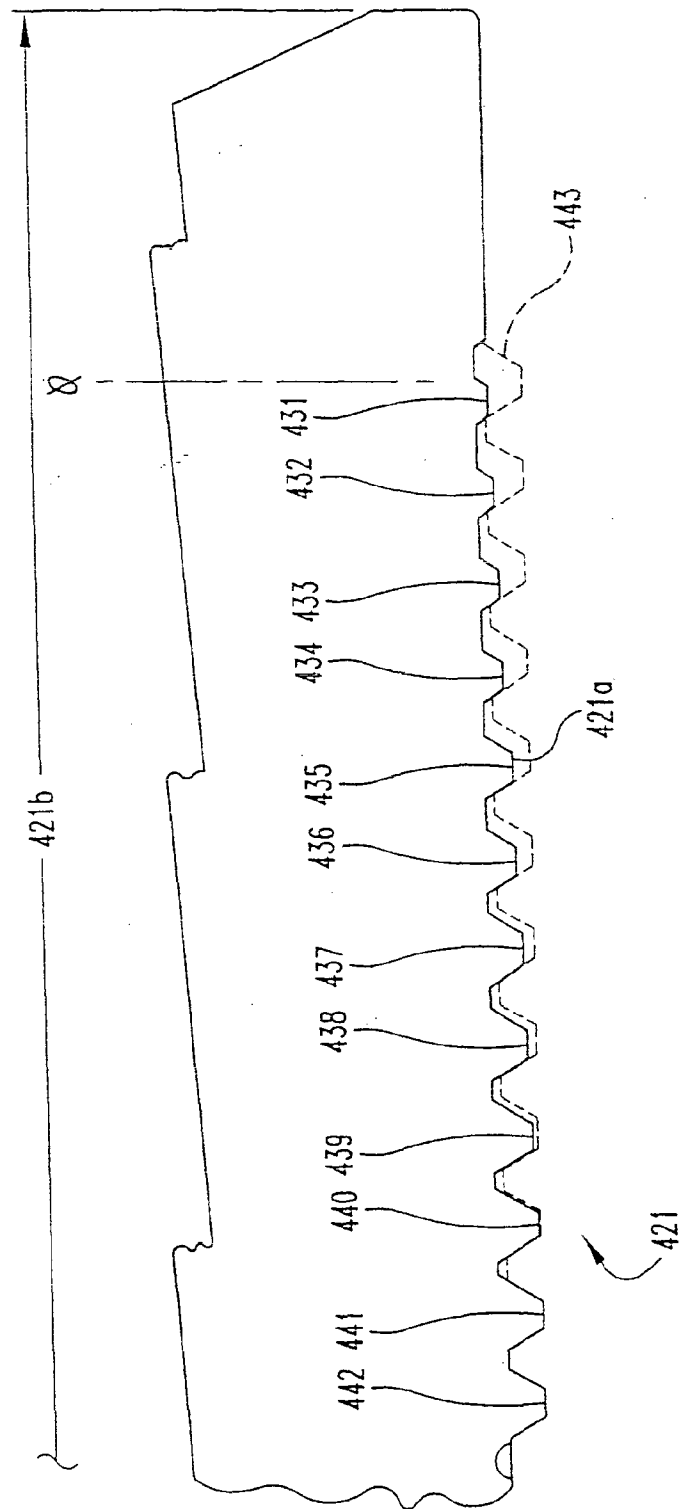


Fig. 22

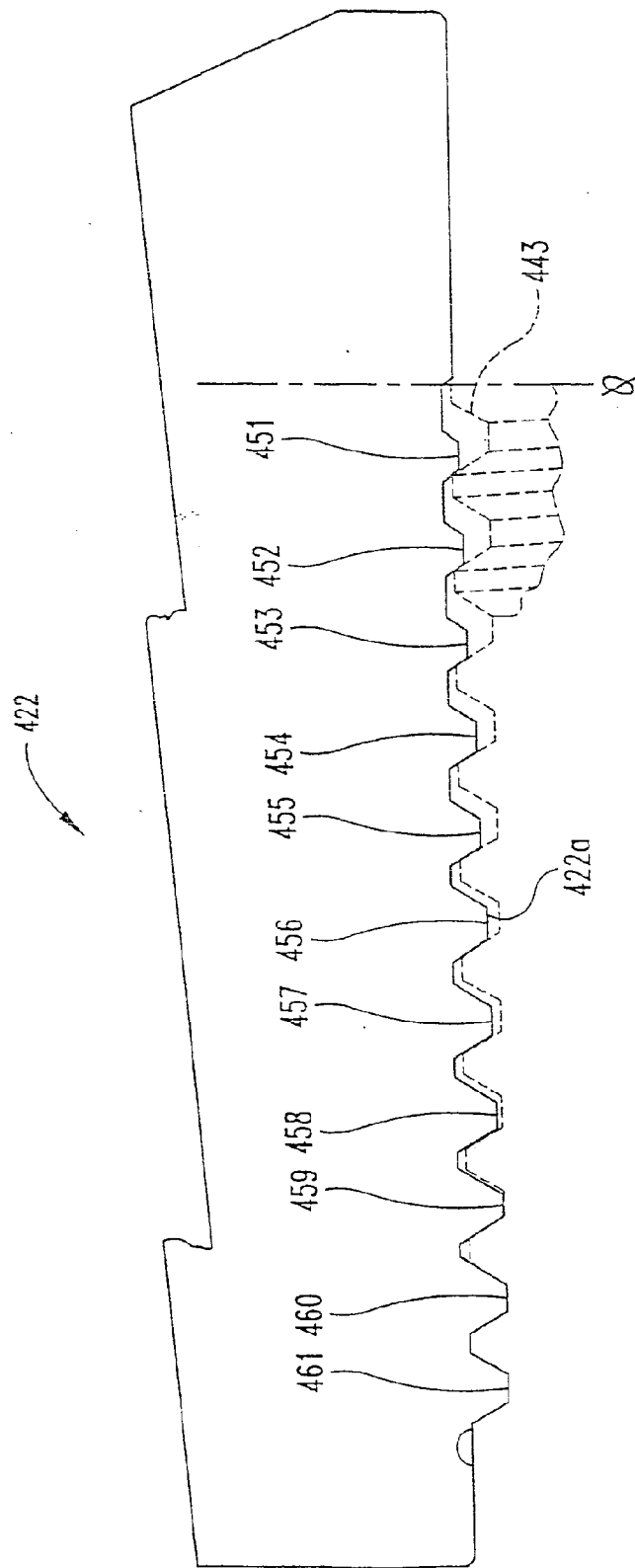
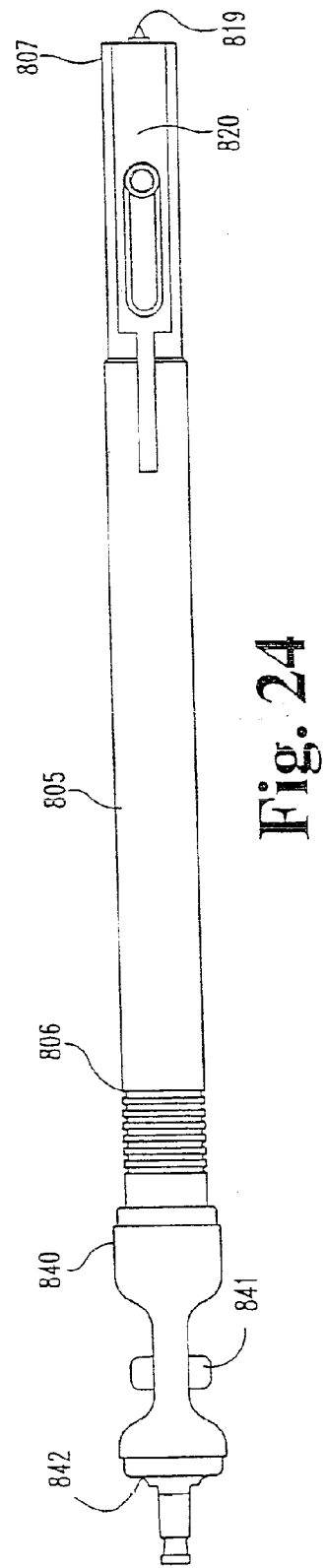
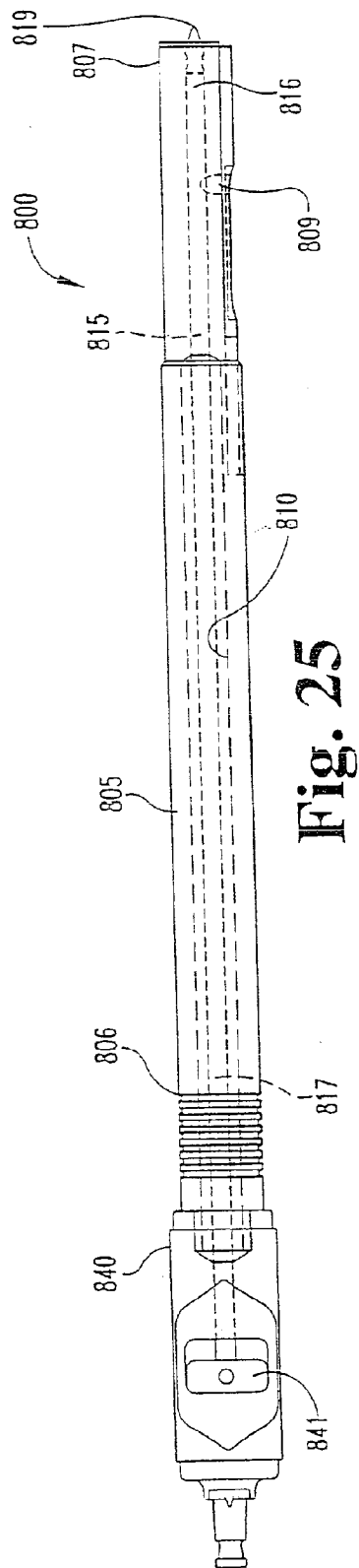


Fig. 23



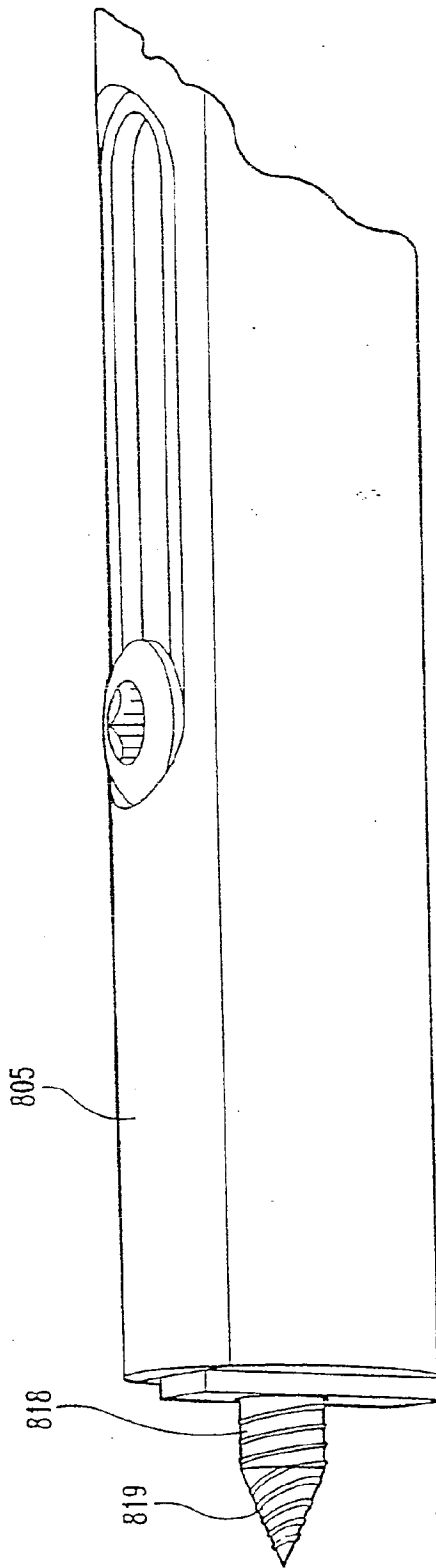


Fig. 26

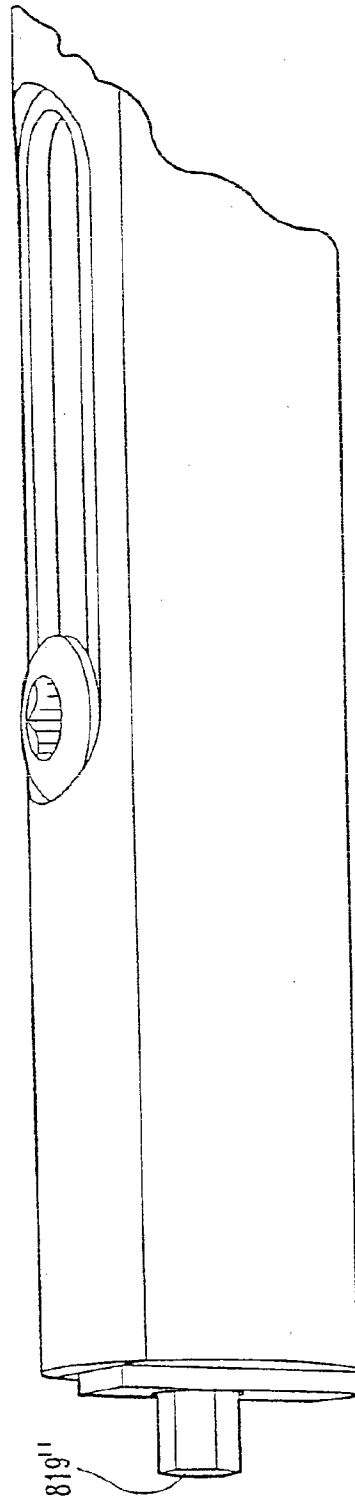


Fig. 27

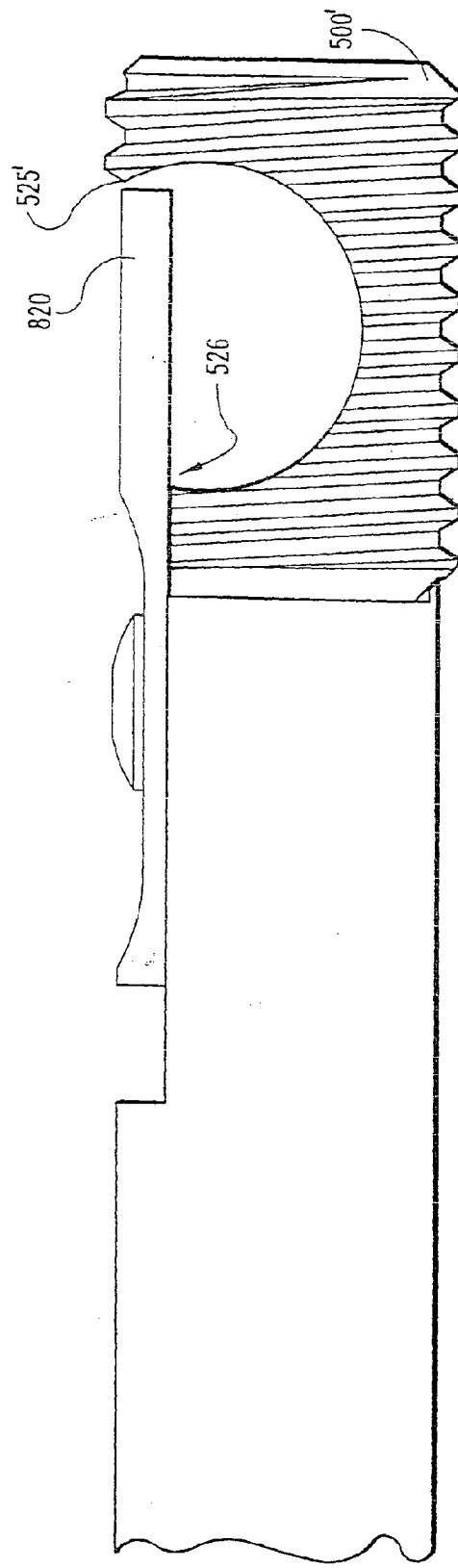


Fig. 28

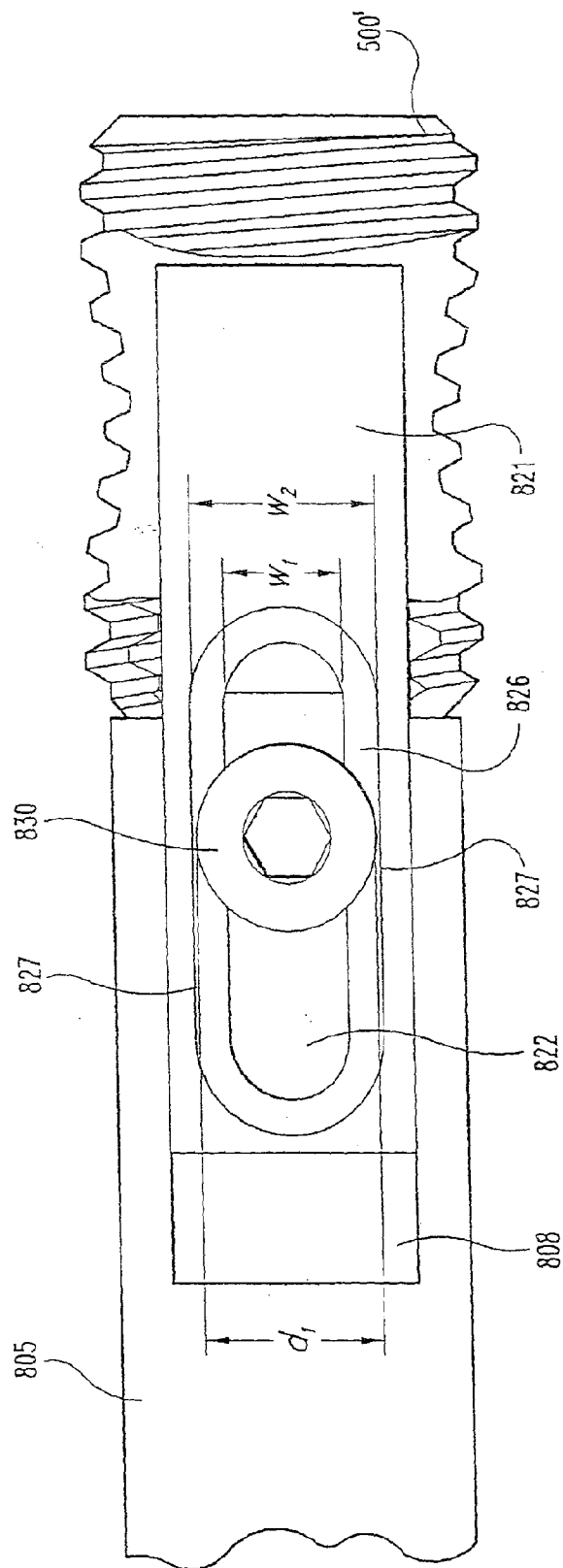


Fig. 29

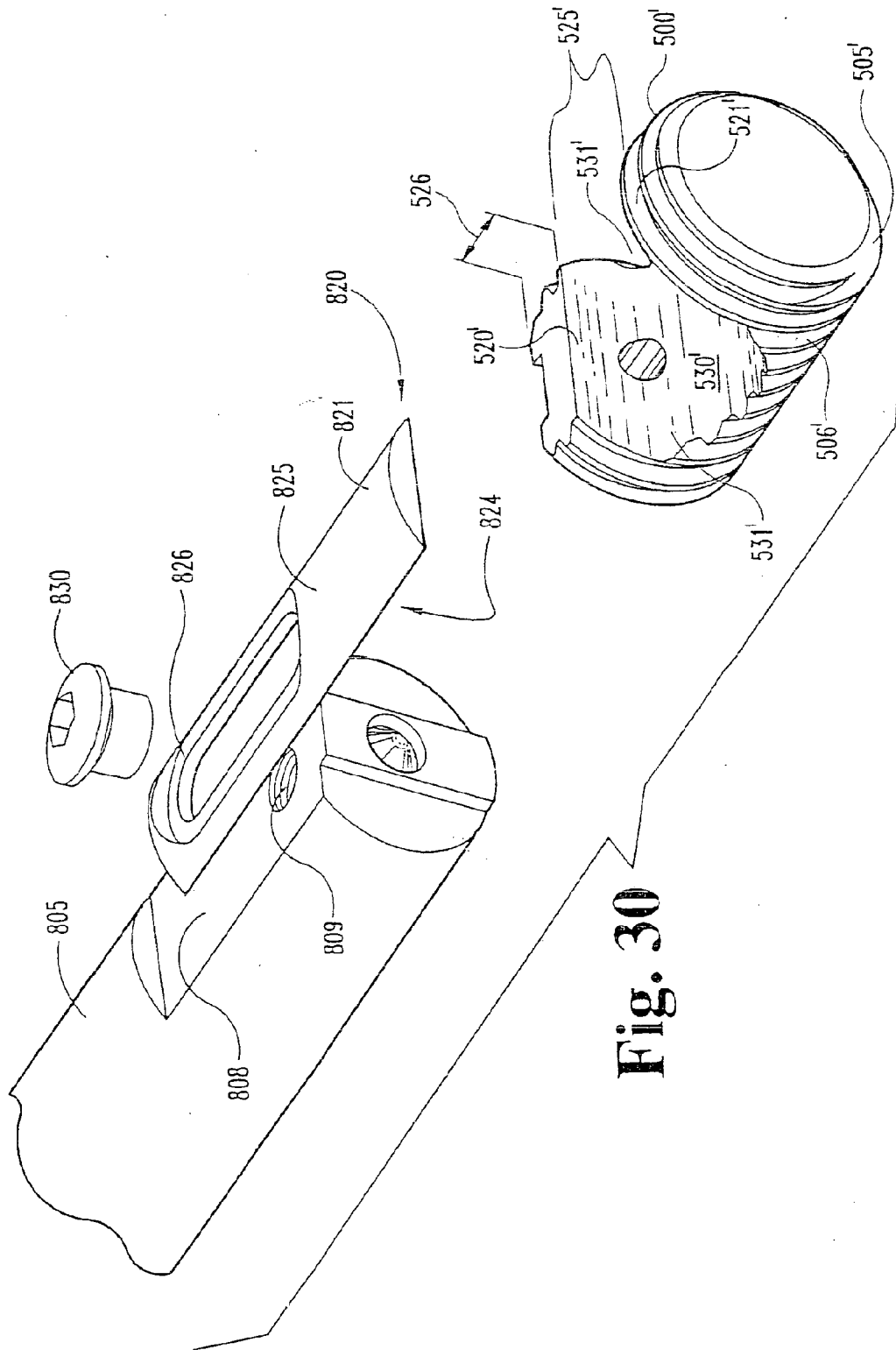


Fig. 30

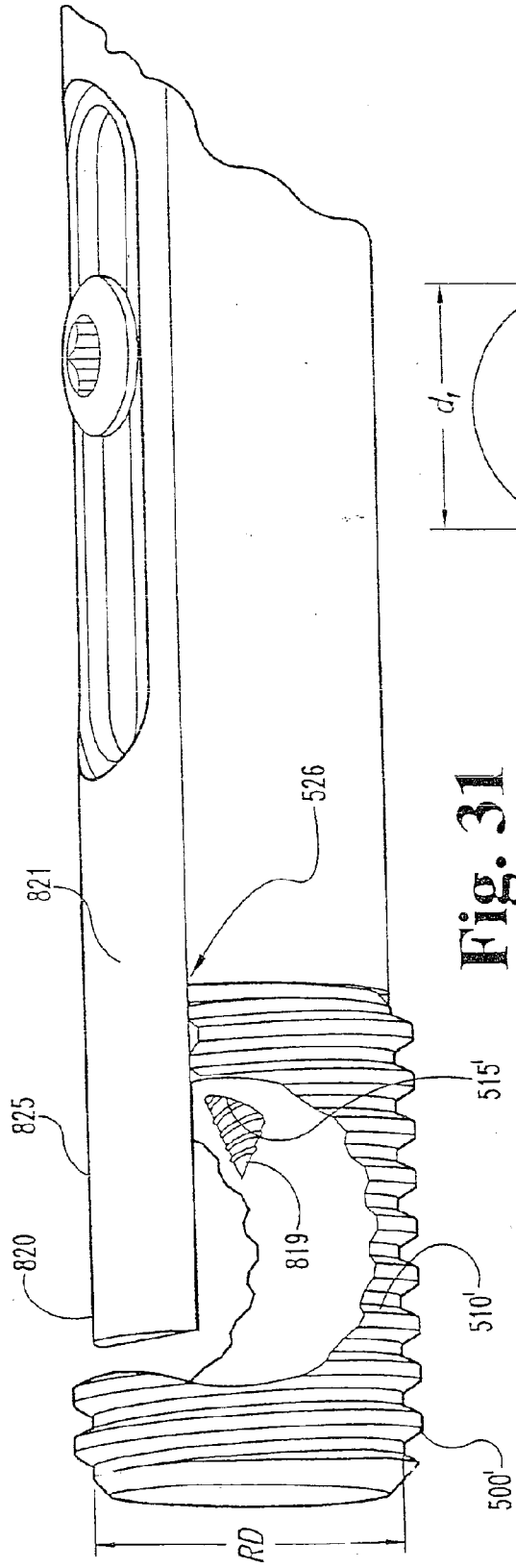


Fig. 31

Fig. 34

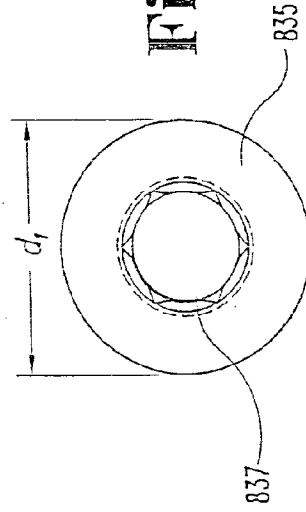


Fig. 33

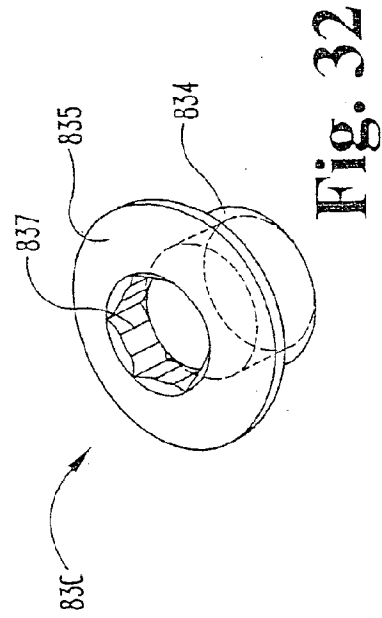
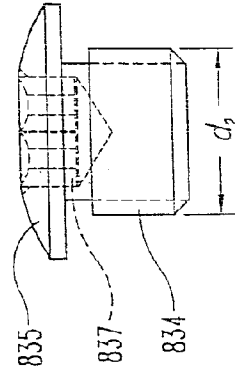


Fig. 32

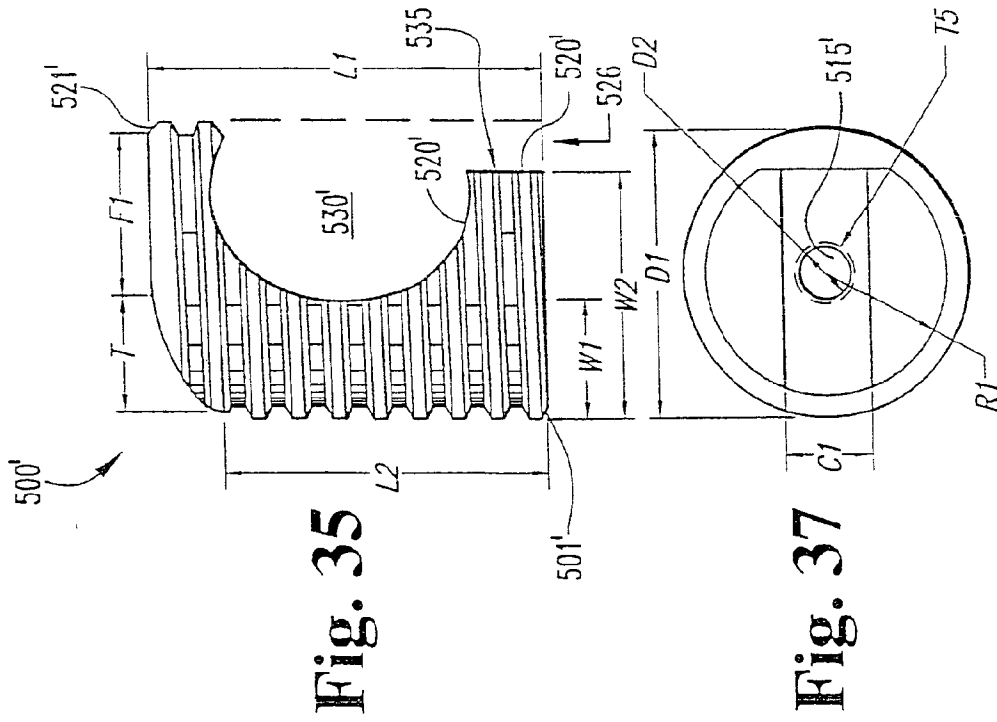


Fig. 35

Fig. 37

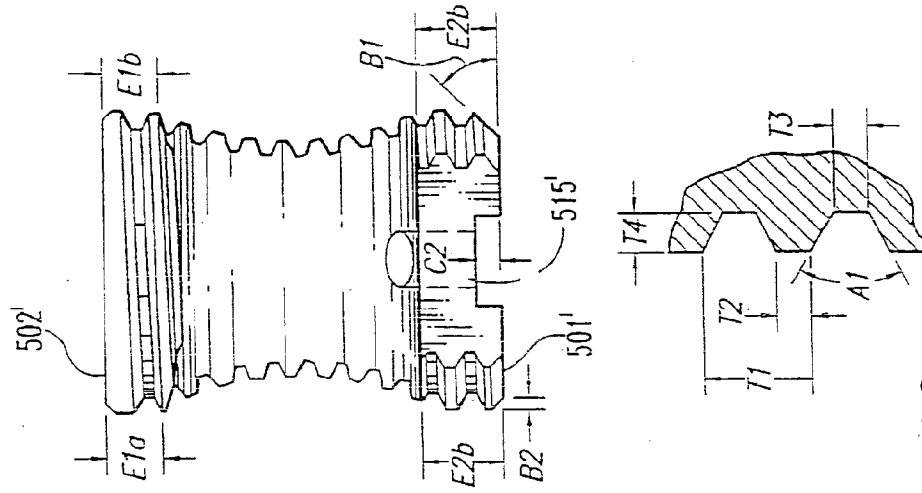


Fig. 36

Fig. 38

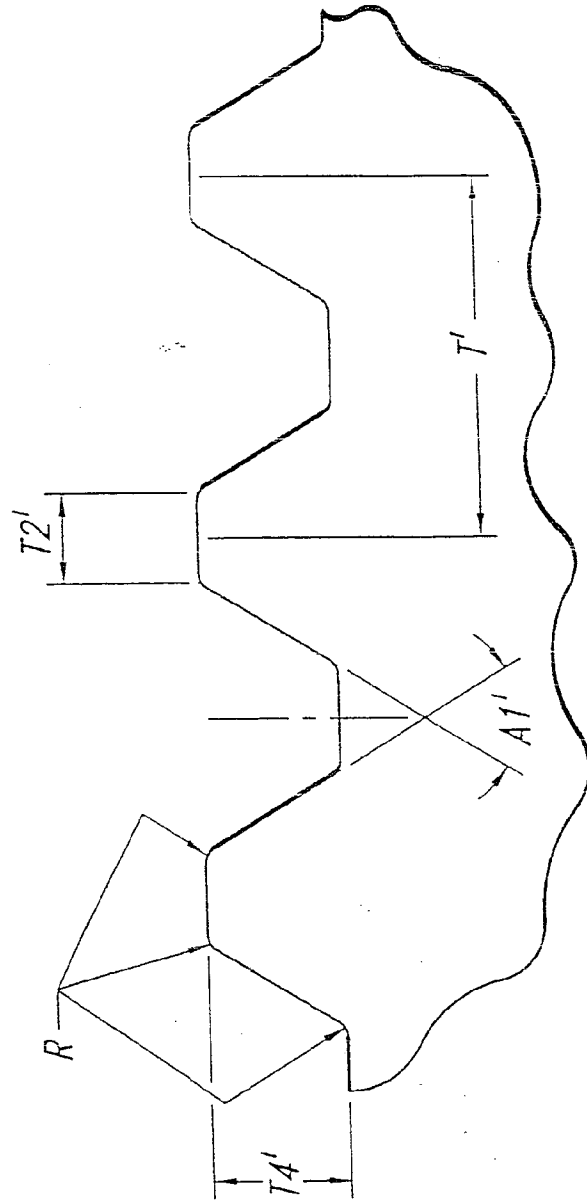


Fig. 39



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PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 03 07 8759 shall be considered, for the purposes of subsequent proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
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			A61F
INCOMPLETE SEARCH			
<p>The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.</p> <p>Claims searched completely : 1-78, 84-87</p> <p>Claims searched incompletely :</p> <p>Claims not searched : 79-83</p> <p>Reason for the limitation of the search: Article 52 (4) EPC - Method for treatment of the human or animal body by surgery</p>			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	24 February 2004	Klein, C	
CATEGORY OF CITED DOCUMENTS		<p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>	
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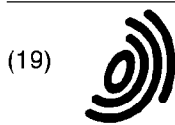
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(54) **Spreizimplantat zur Anordnung zwischen Wirbeln der Wirbelsäule**

(57) Die Erfindung betrifft ein Implantat zur Anordnung zwischen Wirbeln der Wirbelsäule, mit zwei an einem Ende miteinander verbundenen, jeweils gegen einen der Wirbel anlegbaren Schenkeln (12,13) sowie mit einer Einrichtung (19,20) zur vertikalen Distraction der

Schenkel. Erfindungsgemäß konvergieren in der Ausgangsstellung für die Distraction die den Wirbeln zugewandten Außenseiten der Schenkel (12,13) zu den freien Schenkelenden hin. Vorteilhaft erleichtert diese Keilform die Einführung des Implantats in den Zwischenraum zwischen den Wirbeln.

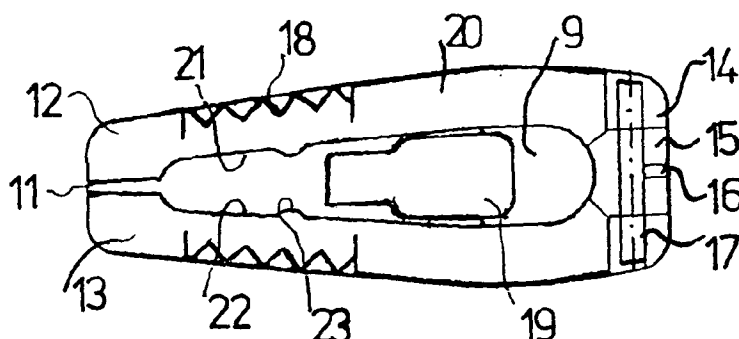


FIG. 3

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Beschreibung

[0001] Die Erfindung betrifft ein Implantat zur Anordnung zwischen Wirbeln der Wirbelsäule, mit zwei an einem Ende miteinander verbundenen, jeweils gegen einen der Wirbel anlegbaren Schenkeln sowie mit einer Einrichtung zur vertikalen Distraktion der Schenkel.

[0002] Implantate solcher Art werden nach Bandscheibenresektionen verwendet, um die betroffenen Wirbel miteinander zu verbinden. Dabei dient das Implantat vorerst als Abstandhalter, welcher den vorher von der Bandscheibe ausgefüllten Zwischenrand ausfüllt. Indem das vorzugsweise mit Durchbrüchen versehene Implantat danach von Knochengewebe durchwachsen und darin eingebettet wird, erfüllt es ferner eine Verbindungsfunktion. Das Implantat fördert die Bildung des die Wirbelkörper verbindenden Knochengewebes.

[0003] Implantate der eingangs erwähnten Art werden vor allem in Bereichen der Wirbelsäule eingesetzt, in denen die einander zugewandten Wirbelkörperendflächen zueinander geneigt sind. Das in den Wirbelzwischenraum eingeführte Implantat wird aufgespreizt, wobei eine Anpassung des Implantats an die zueinander geneigten Wirbelkörperendflächen erfolgt.

[0004] Der vorliegenden Erfindung liegt die Aufgabe zugrunde, ein Implantat der eingangs erwähnten Art zu schaffen, das sich leichter als bekannte solche Implantate handhaben lassen.

[0005] Das diese Aufgabe lösende Implantat nach der Erfindung ist dadurch gekennzeichnet, dass in der Ausgangsstellung für die Distraktion die den Wirbeln zugewandten Außenseiten der Schenkel zu den freien Schenkelenden hin konvergieren.

[0006] Vorteilhaft erleichtert die Keilform des Implantats in der Ausgangsstellung die Einführung des Implantats in den Zwischenraum zwischen den Wirbeln.

[0007] Zweckmäßig sind die miteinander verbundenen Schenkel aus einem einzigen, zur Distraktion verformbaren Kunststoffmaterialstück hergestellt, wobei hierfür z.B. Polyetheretherketon (PEEK) oder auch Titan in Betracht kommt. Vorteilhaft besteht auch der Schieber, der in einer Endstellung, in welcher die Schenkel gespreizt sind, als Abstandhalter zwischen den Schenkeln im Implantat verbleibt, aus diesem hoch belastbaren Kunststoffmaterial.

[0008] In einer Ausführungsform ist vorgesehen, dass die einander zugewandten Schenkelinnenseiten wenigstens abschnittsweise in Richtung zu den freien Schenkelenden konvergieren.

[0009] Diese Ausführungsform mit wenigstens abschnittsweise konvergierenden Innenseiten der Schenkel ermöglicht die Verwendung einer Spreizeinrichtung, die lediglich durch einen zwischen den Schenkeln beweglichen Schieber gebildet ist, welcher bei Verschiebung in Richtung zu den freien Schenkelenden gegen die konvergierenden Schenkelinnenseiten anliegt und so die Schenkel aufspreizt.

[0010] Zweckmäßig ist der Schieber in der genannten Endstellung zur Außenfläche des Implantats bündig, d. h. er fügt sich ohne Absätze in dessen Außenkonturen ein.

[0011] In der bevorzugten Ausführungsform der Erfindung ist das Implantat zur Anordnung in einen seitlichen Halbratim eines nach einer Bandscheibenresektion auszufüllenden Wirbelzwischenraums vorgesehen. Zur Verbindung der Wirbel bedarf es zwei solcher, zueinander spiegelsymmetrischer Implantate. Vorteilhaft lassen sich solche schmalen Implantate vom Rücken her durch den Nervenkanal der Wirbelsäule unter Vorbeiführung am Nervenstrang mit verhältnismäßig geringem Aufwand implantieren.

[0012] Zweckmäßig ist an der den freien Schenkeln gegenüberliegenden Seite des Implantats eine Öffnung für die Durchführung eines Werkzeugs insbesondere zur Betätigung des Schiebers gebildet.

[0013] In weiterer vorteilhafter Ausgestaltung der Erfindung rastet der Schieber in seiner Endstellung ein, wobei vorteilhaft eine lösbare Rastung gebildet ist, die es erlaubt, die Aufspreizung z.B. zwecks genauerer Positionierung des Implantats zwischen den Wirbeln vorübergehend rückgängig zu machen.

[0014] Zweckmäßig weist das Implantat in grober Näherung in seinen Umrissen eine Quaderform auf. Insbesondere die den Wirbeln zugewandten Seiten können jedoch an die Form der einander zugewandten Wirbelloberflächen angepasst sein und das Implantat in Richtung von vorn nach hinten ein Höhenmaximum aufweisen, während die Höhe von der Wirbelmitte zum seitlichen Wirbelrand hin abfällt.

[0015] Die Erfindung soll nun anhand eines Ausführungsbeispiels und der beiliegenden, sich auf dieses Ausführungsbeispiel beziehenden Zeichnungen näher erläutert werden. Es zeigen:

- Fig. 1 eine Teildarstellung eines spreizbaren Implantats nach der Erfindung in einer perspektivischen Ansicht,
- Fig. 2 das um ein Spreizelement ergänzte Implantat von Fig. 1 in einer Draufsicht,
- Fig. 3 das gemäß Fig. 2 ergänzte Implantat in einer Seitenansicht im ungespreizten Zustand, und
- Fig. 4 die Seitenansicht gemäß Fig. 3 im gespreizten Zustand des Implantats.

[0016] Das in den Figuren gezeigte, in grober Näherung quaderförmig Implantat weist eine Oberseite 1, eine Unterseite 2, Längsseiten 3 und 4 sowie Stirnseiten 5 und 6 auf. Die Ecken und Kanten des Implantats sind abgerundet.

[0017] In dem gezeigten Ausführungsbeispiel besteht das Implantat aus Polyetheretherketon (PEEK).

[0018] Eine Abweichung von der Quaderform besteht darin, dass die Implantathöhe von der Stirnseite 5 zur Stirnseite 6 hin bis zu einem Maximum 7 ansteigt und dann wieder abfällt, wobei das Maximum im letzten Drit-

tel der Strecke zwischen den Stirnseiten 5 und 6 liegt.

[0019] In weiterer Abweichung von der Quaderform fällt die Höhe des Implantats von der Längsseite 3 zur Längsseite 4 hin leicht ab. Symmetrie besteht nur in bezug auf eine das Implantat in der Höhenmitte schneidende horizontale Ebene.

[0020] Das Implantat dient zur Ausfüllung eines seitlichen Halbraums zwischen zwei Wirbelkörpern. Im gegenüberliegenden Halbraum wäre ein zu diesem Implantat spiegelsymmetrisches Implantat zu implantieren. Die Implantation erfolgt in Richtung eines Pfeils 8 vom Rücken her durch den Nervenkanal der Wirbelsäule hindurch vorbei am Nervenstrang.

[0021] Das Implantat weist einen horizontalen Durchbruch 9 und einen vertikalen Durchbruch 10 auf, wobei sich die als Langlöcher ausgebildeten Durchbrüche 9 und 10 kreuzen. An der Stirnseite 5 ist eine weitere, nach innen zu den Durchbrüchen 9 und 10 öffnende Schlitzausnehmung 11 vorgesehen.

[0022] Durch den horizontalen Durchbruch 10 und die Schlitzausnehmung 11 sind vertikal bewegliche Schenkel 12 und 13 gebildet, die über einen Steg 14 an der Stirnseite 6 miteinander verbunden sind.

[0023] Der Steg 14 weist eine Durchgangsbohrung 15 mit einer Schlitzansenkung 16 auf. Die Durchgangsbohrung 15 öffnet nach innen sowohl zu dem horizontalen Durchbruch 9 als auch dem vertikalen Durchbruch 10.

[0024] Neben der Durchgangsbohrung 15 ist senkrecht eine weitere Durchgangsbohrung 17 in dem Steg 14 für die Aufnahme eines Metallstifts gebildet. An der Ober- und Unterseite des Implantats ist jeweils eine Zahnung 18 vorgesehen, deren Zahnkämme sich quer zur Längsrichtung des Implantats von der Längsseite 4 bis zu dem vertikalen Durchbruch 10 erstrecken.

[0025] Mit dem Bezugszeichen 19 ist ein zwischen den Schenkeln 12 und 13 angeordneter, ein Spreizelement bildender Schieber bezeichnet, welcher bündig mit den Längsseiten 3 und 4 des Implantats abschließt. Auch der Schieber ist wie das die Schenkel 12 und 13 sowie den Steg 14 bildende Materialstück einstückig aus PEEK hergestellt.

[0026] Von der Ober- und Unterseite des Schiebers 19 steht jeweils ein Führungszapfen 20 vor, welcher in den oberen bzw. unteren Abschnitt des vertikalen Durchbruchs 10 eingreift.

[0027] Bei Verschiebung in Richtung zu den freien Enden der Schenkel 12 und 13 kommt der Schieber 19 gegen konvergierende, einander gegenüberliegende Innenseiten 21 und 22 der Schenkel 12 und 13 zur Anlage. Von den Innenseiten 21 und 22 steht jeweils eine Rastnase 23 vor.

[0028] Bei der Implantation befindet sich der Schieber 19 zunächst etwa in der in Fig. 3 gezeigten Position. Das die Schenkel 12 und 13 sowie den Steg 14 bildende Materialstück ist in diesem Zustand unverformt. Die Schenkel 12 und 13 bilden einen stumpfen Keil, der es erleichtert, das Implantat in den Zwischenraum zwischen zwei Wirbeln einzuführen.

[0029] In der Implantationsposition zwischen den Wirbeln wird der Schieber 19 mit Hilfe eines durch die Durchgangsbohrung 15 geführten, ggf. in die Schlitzansenkung eingreifenden Werkzeugs in Richtung zu den freien Schenkelenden verschoben, wobei der gleitbeweglich gegen die konvergierenden Innenseiten 21 und 22 anliegende Schieber die Schenkel 12 und 13 aufspreizt. Wie insbesondere Fig. 2 zu entnehmen ist, liegt der Führungszapfen 20 mit Seitenflächen gegen die Innenwand des vertikalen Durchbruchs 10 an, so dass der Schieber 19 zwischen den Schenkeln 12 und 13 verdrehsicher geführt ist.

[0030] In der in Fig. 4 gezeigten Endstellung ist der Schieber 19 hinter den Rastnasen 23 eingerastet. In dieser Stellung fügt er sich in das Implantat bündig mit dessen Außenfläche ein und bildet auf der Stirnseite 5 einen Abstandhalter, der das Implantat in der in Fig. 4 gezeigten Form festhält, in welcher das die Schenkel 12 und 13 sowie den Steg 14 bildende einstückige Kunststoffteil elastisch verformt ist.

[0031] Der Schieber 19 könnte an seiner der Durchgangsbohrung 15 zugewandten Seite für den Angriff eines Werkzeugs geeignete Vertiefungen oder Vorsprünge insbesondere derart aufweisen, dass er sich aus der in Fig. 4 gezeigten Position zurückziehen lässt, z.B. um das Implantat lösen und zwischen den Wirbelkörpern in einer neuen Position platzieren zu können.

[0032] Durch die Bohrung 15 läßt sich auch ein Werkzeug führen, mit dessen Hilfe in den dem Durchbruch 10 gegenüberliegenden Wirbelbereichen Knochenweichgewebe frei gelegt werden kann. Das Knochenweichgewebe bildet dann neues, den Durchbruch 10 durchsetzendes Knochengewebe.

[0033] In dem in Fig. 4 gezeigten Zustand dringt die Zahnung 18 in gegen das Implantat anliegendes Knochenhartgewebe ein, wodurch eine sichere Arretierung des Implantats zwischen den Wirbelkörpern erreicht wird.

[0034] Zweckmäßig liegt die Zahnung 18 so weit wie möglich vom Nervenkanal und der Hauptbelastungsachse der Wirbelsäule entfernt, so dass durch das Eindringen in das Knochengewebe weder Nervenbahnen verletzt werden noch die Tragfähigkeit der Wirbelsäule beeinträchtigt wird.

[0035] In dem gezeigten Ausführungsbeispiel ist die Implantathöhe an der Stirnseite 5 im aufgespreizten Zustand so groß wie an der gegenüberliegenden Stirnseite 6. Die den Wirbelkörpern zugewandten Außenseiten der Schenkel könnten in ihrem Dickenprofil in Längsrichtung des Implantats jedoch auch so ausgebildet sein, dass die Implantathöhe im gespreizten Zustand an der Stirnseite 5 größer oder kleiner als an der Stirnseite 6 ist, um eine Anpassung an zueinander geneigte Wirbel insbesondere im lumbalen Bereich der Wirbelsäule zu erreichen.

[0036] Der Schieber 19 könnte eine zu den Längsseiten 3 und 4 öffnende Durchgangsbohrung für die Aufnahme eines weiteren, zu dem Metallstift in der Bohrung

17 senkrecht angeordneten Metallstifts aufweisen, so dass anhand zweier solcher, sich im Röntgenbild gut abhebender Stifte die räumliche Position des Implantats genau beurteilt werden kann.

[0037] Die zur Führung des Schiebers 19 dienenden Durchbrüche 9 und 10 können nach der Implantation vom Knochengewebe durchwachsen werden, wobei das Implantat weitgehend in die Wirbel miteinander verbindendes Knochengewebe eingebettet wird.

Patentansprüche

1. Implantat zur Anordnung zwischen Wirbeln der Wirbelsäule, mit zwei an einem Ende miteinander verbundenen, jeweils gegen einen der Wirbel anlegbaren Schenkeln (12,13) sowie mit einer Einrichtung (19,20) zur vertikalen Distraction der Schenkel, **dadurch gekennzeichnet, dass** in der Ausgangsstellung für die Distraction die den Wirbeln zugewandten Außenseiten der Schenkel (12,13) zu den freien Schenkelen hin konvergieren.

2. Implantat nach Anspruch 1, **dadurch gekennzeichnet, dass** die miteinander verbundenen Schenkel (12,13) aus einem einzigen, zur Distraction verformbaren Materialstück, vorzugsweise aus einem Kunststoff, hergestellt sind.

3. Implantat nach Anspruch 2, **dadurch gekennzeichnet, dass** der Kunststoff Polyetheretherketon (PEEK) ist.

4. Implantat nach einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet, dass** die einander zugewandten Schenkelninnenseiten (21,22) wenigstens abschnittsweise in Richtung zu den freien Schenkelen konvergieren.

5. Implantat nach Anspruch 4, **dadurch gekennzeichnet, dass** die Einrichtung (19,20) zur vertikalen Distraction einen zwischen den Schenkeln (12,13) angeordneten, gegen die konvergierenden Schenkelninnenseiten anlegbaren Schieber (19) aufweist.

6. Implantat nach Anspruch 5, **dadurch gekennzeichnet, dass** an der den freien Schenkelen gegenüberliegenden Seite des Implantats eine Öffnung (16) für die Durchführung eines ggf. den Schieber (19) betätigenden Werkzeugs gebildet ist.

7. Implantat nach Anspruch 5 oder 6, **dadurch gekennzeichnet,**

dass der Schieber (19) in einer Endstellung, in der die Schenkel (12,13) gespreizt sind, vorzugsweise lösbar, einrastet.

8. Implantat nach einem der Ansprüche 5 bis 7, **dadurch gekennzeichnet, dass** der Schieber in einer Endstellung, in der die Schenkel (12,13) gespreizt sind, sich in das Implantat bündig zu dessen Außenfläche einfügt.

9. Implantat nach einem der Ansprüche 1 bis 8, **dadurch gekennzeichnet, dass** das Implantat zur Anordnung in einem seitlichen Halbraum zwischen zwei Wirbeln in Verbindung mit einem dazu spiegelsymmetrischen, in dem anderen Halbraum angeordneten solchen Implantat vorgesehen ist.

10. Implantat nach einem der Ansprüche 1 bis 9, **dadurch gekennzeichnet, dass** der Schieber in einem als Langloch ausgebildeten vertikalen Durchbruch des Implantats geführt ist.

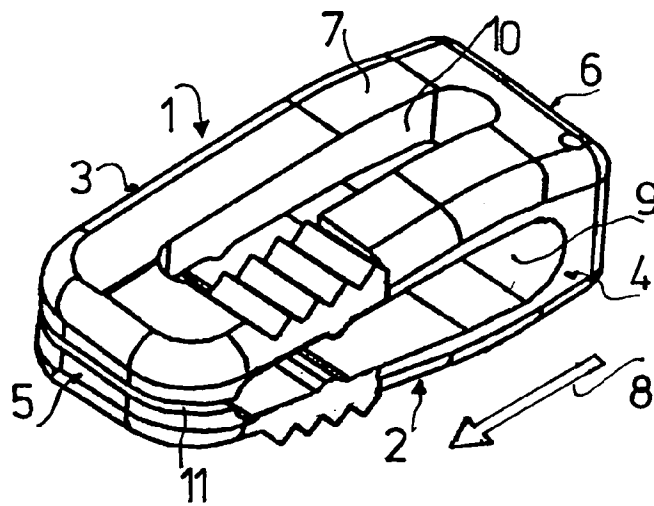


FIG. 1

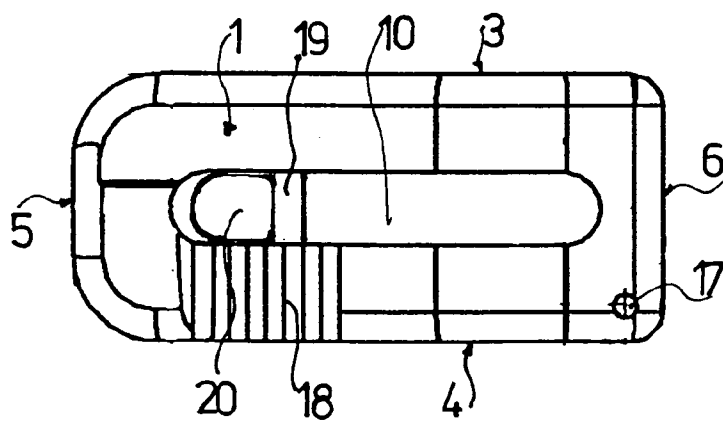


FIG. 2

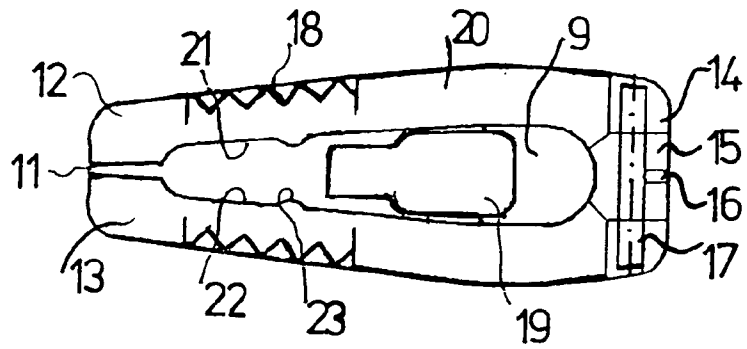


FIG. 3

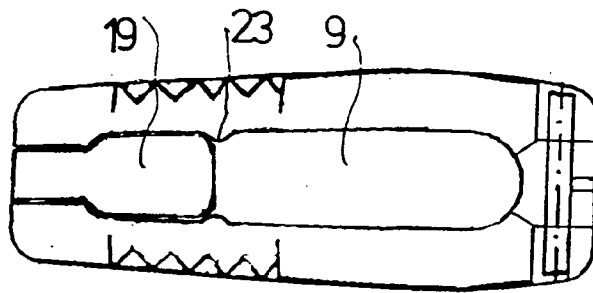


FIG. 4



Europäisches
Patentamt

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 03 02 1883

EINSCHLÄGIGE DOKUMENTE			
Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int.Cl.7)
X	FR 2 803 741 A (BOUVET JEAN CLAUDE) 20. Juli 2001 (2001-07-20) * Ansprüche 1,5,7; Abbildungen *	1-6	A61F2/44
A	---	7,8	
X	US 6 454 807 B1 (JACKSON ROGER P) 24. September 2002 (2002-09-24) * Abbildungen * * Spalte 8, Zeile 47 - Spalte 9, Zeile 67 *	1,3-6,9	
Y	---	7,8	
X	FR 2 771 282 A (TAYLOR JEAN) 28. Mai 1999 (1999-05-28) * Ansprüche 1,2,8,10; Abbildungen *	1,4-6	
A	---	7	
Y	US 6 117 174 A (NOLAN WESLEY A) 12. September 2000 (2000-09-12) * Abbildungen 6A,8,15,16 * * Spalte 6, Zeile 3 - Zeile 29 *	7,8	
A	---	1,2,4-6,9	RECHERCHIERTE SACHGEBIETE (Int.Cl.7) A61F
A	US 2002/068976 A1 (JACKSON ROGER P) 6. Juni 2002 (2002-06-06) * Anspruch 1; Abbildungen * -----	1,5,6,8,10	
Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt			
Rechenort BERLIN		Abschlußdatum der Recherche 20. Februar 2004	Prüfer Stach, R
<p>KATEGORIE DER GENANNTEN DOKUMENTE</p> <p>X : von besonderer Bedeutung allein betrachtet Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie A : technologischer Hintergrund O : mündliche Offenbarung P : Zwischenliteratur</p> <p>T : der Erfindung zugrunde liegende Theorien oder Grundsätze E : älteres Patentdokument, das jedoch erst am oder nach dem Anmeldedatum veröffentlicht worden ist D : in der Anmeldung angeführtes Dokument L : aus anderen Gründen angeführtes Dokument & : Mitglied der gleichen Patentfamilie, übereinstimmendes Dokument</p>			

EPO FORM 1503 03.82 (P04C03)

**ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT
ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR.**

EP 03 02 1883

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten europäischen Recherchenbericht angeführten Patentedokumente angegeben.

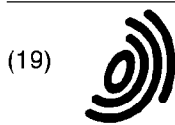
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am
Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

20-02-2004

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Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82



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(54) Implantat für die Anordnung zwischen Wirbeln der Wirbelsäule

(57) Die Erfindung betrifft ein Implantat für die Anordnung zwischen Wirbeln der Wirbelsäule, wie es insbesondere bei der Verbindung von Wirbeln nach einer Bandscheibenresektion zur Anwendung kommt. Erfindungsgemäß ist eine Formanpassung des Implantats

an eine bestehende Vertiefung in den dem Implantat zugewandten Wirbeloberflächen vorgesehen. Diese Anpassung an die geringfügig eingefallene Wirbeloberfläche führt zu einer geringeren Beanspruchung der Wirbelkörper durch das Implantat und sorgt für eine hohe Lagestabilität des Implantats zwischen den Wirbeln.

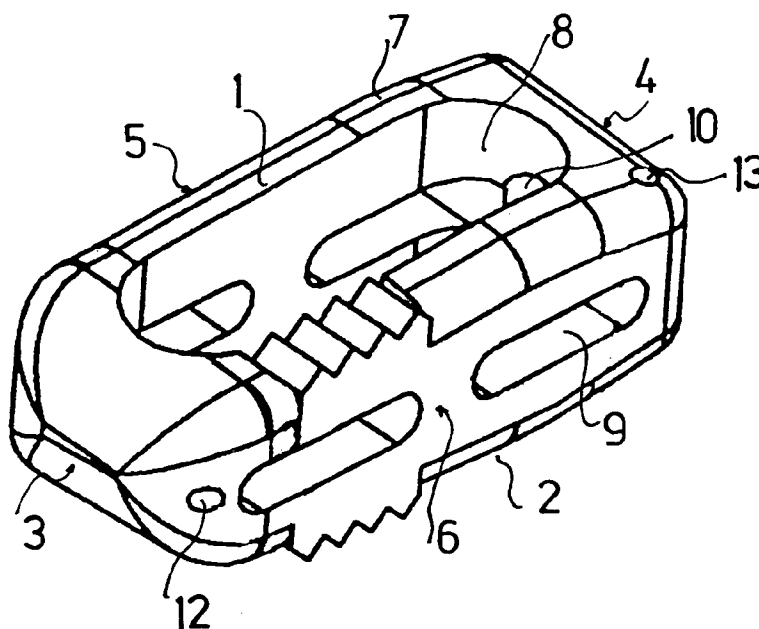


FIG.1

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Beschreibung

[0001] Die Erfindung betrifft ein Implantat für die Anordnung zwischen Wirbeln der Wirbelsäule.

[0002] Implantate für die Anordnung zwischen Wirbeln der Wirbelsäule kommen zur Anwendung, wenn nach Resektion einer Bandscheibe die betroffenen Wirbel unter Überbrückung des zwischen ihnen entstandenen Zwischenraums miteinander zu verbinden sind. Hierbei dient das Implantat einerseits als Abstandhalter. Dem mit Durchbrüchen versehenen Implantat kommt ferner eine Verbindungsfunktion zu, indem es von Knochengewebe durchdrungen und eine das Implantat einschließende Knochengewebsverbindung zwischen Wirbeln gebildet wird.

[0003] Der Erfindung liegt die Aufgabe zugrunde, ein neues Implantat der eingangs erwähnten Art zu schaffen, das in bezug auf die obengenannten Funktionen verbessert ist.

[0004] Das diese Aufgabe lösende Implantat nach der Erfindung ist gekennzeichnet durch eine Formanpassung des Implantats an eine Vertiefung in den dem Implantat zugewandten Wirbeloberflächen.

[0005] Erfindungsgemäß wird bei der Form des Implantats berücksichtigt, dass die dem Implantat zugewandten Wirbeloberflächen nicht eben, sondern leicht eingefallen sind. Überraschend führt diese Formanpassung zu einer wesentlichen Verbesserung der Lagestabilität des Implantats zwischen den Wirbeln. Ferner werden hohe Flächenpressungen und damit Beanspruchungen des Knochengewebes durch das Implantat vermieden. Beide Faktoren fördern ein schnelles und problemloses Wachstum des Verbindungsknochengewebes unter Durchdringung des Implantats.

[0006] Eine solche Formanpassung kann gemäß einem Ausführungsbeispiel für die Erfindung darin bestehen, dass in Richtung von der Vorder- zur Rückseite der Wirbelsäule die Höhe des Implantats bis zu einem Maximum ansteigt und wieder abnimmt, wobei entsprechend des Vertiefungsprofils der Wirbeloberfläche das Maximum vorzugsweise im letzten Drittel der betreffenden Implantatlänge liegt.

[0007] Eine noch weitergehend komplementäre Gegenfläche zur Wirbeloberfläche weist das Implantat auf, wenn ferner in Richtung senkrecht zu einer die Wirbelsäule von vorn nach hinten durchstoßenden Mittelachse die Höhe des Implantats zu der Mittelachse hin ansteigt. Diese Formanpassung berücksichtigt, dass die Wirbeloberfläche etwa die Form eines Schrögdachs mit einer bis zu dem Maximum ansteigenden und dann wieder abfallenden Firstlinie aufweist.

[0008] Vorzugsweise ist das Implantat entsprechend der Symmetrie der einander zugewandten Wirbeloberflächen in bezug auf eine die Wirbelsäulenlängsachse senkrecht schneidende Ebene symmetrisch ausgebildet.

[0009] In einer besonders bevorzugten Ausführungsform der Erfindung ist das Implantat zur Anordnung in

einem Halbraum des Zwischenraums zwischen den Wirbeln gemeinsam mit einem zweiten, zu dem Implantat spiegelsymmetrischen solchen Implantat vorgesehen. Vorteilhaft lässt sich jedes dieser Implantate dann von der Rückenseite her durch den Nervenkanal hindurch unter Vorbeiführung am Nervenstrang der Wirbelsäule in den Zwischenraum zwischen den Wirbeln einführen. Ein den gesamten Wirbelzwischenraum ausfüllendes solches Implantat könnte nur von vorn eingesetzt werden.

[0010] In weiterer Ausgestaltung der Erfindung kann das Implantat Vorsprünge für die Arretierung am Knochengewebe der Wirbel aufweisen, wobei diese Vorsprünge zur weiteren Stabilisierung der Lage des zwischen den Wirbeln angeordneten Implantats beitragen.

[0011] Zweckmäßig sind solche Arretierungsvorsprünge in größtmöglicher Entfernung vom Nervenkanal oder/und der Hauptbelastungsachse der Wirbelsäule angeordnet. Mit dem Eindringen der Arretierungsvorsprünge in das Knochengewebe besteht somit weder die Gefahr der Verletzung von Nervenbahnen noch einer Beeinträchtigung der Wirbelsäulenstabilität.

[0012] In einer bevorzugten Ausführungsform der Erfindung sind solche Arretierungsvorsprünge durch eine Zahnung gebildet.

[0013] In weiterer vorteilhafter Ausgestaltung der Erfindung kann eine in Implantationsrichtung vordere Stirnfläche des Implantats nach vorn ausgewölbt sein. Eine solche Auswölbung erleichtert die Einführung des Implantats in den Zwischenraum zwischen den Wirbeln. In der bevorzugten Ausführungsform der Erfindung ist das Implantat in der Art eines Käfigs hohl mit Wanddurchbrüchen ausgebildet.

[0014] In weiterer vorteilhafter Ausgestaltung der Erfindung ist das Implantat in der Draufsicht rahmenartig mit einem zur Ober- und Unterseite des Implantats offenen Durchbruch als Rahmenöffnung ausgebildet. In den Durchbruch kann von der Ober- und Unterseite her Verbindungsknochengewebe einwachsen, wobei auch eine Durchdringung von Öffnungen in den Seiten des Implantats unter weitgehender Einbettung des Implantats in Knochengewebe erfolgen kann.

[0015] In der bevorzugten Ausführungsform der Erfindung besteht das Implantat aus einem Kunststoff, vorzugsweise Polyetheretherketon (PEEK). Im Unterschied zu metallischen Werkstoffen ist das Kunststoffmaterial ähnlich nachgiebig wie Knochengewebe und fügt sich daher besser als Metall organisch in das Knochengewebe ein.

[0016] Die Erfindung soll nun anhand eines Ausführungsbeispiels und der beiliegenden, sich auf dieses Ausführungsbeispiel beziehenden Zeichnungen näher erläutert werden. Es zeigen:

- Fig. 1 ein erfindungsgemäßes Implantat in einer perspektivischen Darstellung,
- Fig. 2 das Implantat von Fig. 1 in einer Draufsicht,
- Fig. 3 das Implantat von Fig. 1 in einer Längsseiten-

- darstellung,
 Fig. 4 das Implantat von Fig. 1 in einer Stirnseiten-
 darstellung,
 Fig. 5 das Implantat von Fig. 1 in einer geschnittenen
 Draufsicht,
 Fig. 6 das Implantat von Fig. 1 in einer geschnittenen
 Stirnseitendarstellung, und
 Fig. 7 Implantate gemäß Fig. 1 im implantierten Zu-
 stand zwischen Wirbeln der Wirbelsäule.

[0017] Das in den Fig. 1 bis 7 gezeigte Implantat weist in seinen Umrissen die Form eines länglichen Quaders mit einer Oberseite 1, einer Unterseite 2, Stirnseiten 3 und 4 sowie Längsseiten 5 und 6 auf.

[0018] Die Stirnseite 3 des an seinen Ecken und Kanten abgerundeten Quaders ist vorgewölbt, während die der Stirnseite 3 gegenüberliegende Stirnseite 4 eben ist.

[0019] In weiterer Abweichung von der Quaderform nimmt die Höhe des Implantats in Längsrichtung von der Stirnwand 3 an zu, erreicht bei 7 ein Maximum und fällt in dem gezeigten Ausführungsbeispiel bis zur Stirnseite 4 wieder ab. Das Implantathöhenmaximum bei 7 liegt von der Stirnseite 3 aus gesehen im letzten Drittel der Länge des Implantats.

[0020] Schließlich weicht das Implantat in seinen Umrissen von der Quaderform noch dadurch ab, dass sich die Implantathöhe quer zur Längsrichtung von der Längsseite 5 zur Längsseite 6 hin verringert. In diesem Ausführungsbeispiel beträgt bei einer Maximalhöhe des Implantats von 9,5 mm diese Höhenabnahme ca. 2 mm.

[0021] In dem Bereich von der Stirnseite 3 bis zum Implantathöhenmaximum bei 7 sind die Oberseite 1 und die Unterseite 2 des Implantats bezogen auf dessen Längsachse zueinander um 6° geneigt. Die entsprechende Neigung im Bereich zwischen dem Implantatmaximum und der Stirnseite 4 beträgt 16°.

[0022] In Bezug auf vertikale Ebenen besteht also keine Symmetrie. Das Implantat ist jedoch zu einer horizontalen Ebene symmetrisch, welche das Implantat in dessen Höhenmitte schneidet.

[0023] Wie aus den Fig. 1 bis 7 hervorgeht, weist das Implantat einen zur Oberseite 1 und Unterseite 2 öffnenden vertikalen Durchbruch 8 auf, welcher das Implantat in den Draufsichten von Fig. 2, 5 und 7 rahmenartig aussehen lässt, wobei der vertikale Durchbruch 8 die Rahmenöffnung bildet. Wie den Figuren zu entnehmen ist, weist der vertikale Durchbruch 8 die Form eines an seinen Enden gerundeten Langlochs auf.

[0024] An den Längsseiten 5 und 6 sind jeweils zwei Durchbrüche 9 gebildet, welche zu dem vertikalen Durchbruch 8 hin öffnen und wie dieser die Form eines Langlochs mit gerundeten Enden aufweisen.

[0025] An der Stirnseite 4 ist eine zu dem vertikalen Durchbruch 8 öffnende Bohrung 10 gebildet. Diese Bohrung 10 weist eine Einsenkung in Form eines Schlitzes 11 mit sich diametral zur Bohrungsöffnung erstreckenden Schlitzabschnitten auf.

[0026] Mit den Bezugszeichen 12 und 13 sind Durch-

gangsbohrungen mit zueinander senkrechten Bohrungssachsen bezeichnet. Die Bohrungen dienen zur Aufnahme von im Röntgenbild gut sichtbaren Metallstiften, insbesondere Titanstiften.

[0027] Angrenzend an die Längsseite 6 ist an der Oberseite 1 und der Unterseite 2 des Implantats jeweils eine Zahnung 14 gebildet, deren Zahnkämme sich durchgehend von der Längsseite 6 bis zu dem vertikalen Durchbruch 8 erstrecken. Wie insbesondere Fig. 3 zu entnehmen ist, entspricht der Abstand zwischen den Zahnkämmen einander entsprechender Zähne an der Unter- und Oberseite des Implantats der jeweiligen Implantathöhe auf der gegenüberliegenden Längsseite 5.

[0028] Im folgenden wird die Funktion des vorangehend beschriebenen Implantats unter Bezugnahme auf Fig. 7 erläutert.

[0029] Fig. 7 zeigt zwei zwischen Wirbeln 17 der Wirbelsäule 15 angeordnete Implantate 16 und 16', von denen das Implantat 16 mit dem vorangehend anhand der Fig. 1 bis 6 beschriebenen Implantat übereinstimmt. Das Implantat 16' ist zu dem Implantat 16 spiegelsymmetrisch.

[0030] Die Einführung der Implantate in den Zwischenraum zwischen den Wirbelkörpern erfolgt in Richtung des in Fig. 7 eingezeichneten Pfeils unter Vorbeiführung des Implantats am Nervenstrang im Nervenkanal (nicht gezeigt) der Wirbelsäule 15. Die Wölbung der Stirnseite 3 erleichtert das Eindringen der Implantate in den Zwischenraum zwischen den Wirbelkörpern, die während der Implantation zur Freihaltung dieses Zwischenraums durch geeignete Halter abzustützen sind.

[0031] Zur Einführung des Implantats 16 bzw. 16' in den Zwischenraum zwischen den Wirbeln kann das Implantat durch ein Werkzeug bewegt werden, welches durch die Bohrung 10 hindurch in das Implantat eingreift und für das der Schlitz 11 einen Sitz bildet, der Implantat und Werkzeug gegen Verdrehung zueinander sichert.

[0032] In der in Fig. 7 gezeigten Stellung lässt sich durch die Bohrung 10 hindurch ein Schabwerkzeug für die Abtragung von Hartknorpelgewebe im Bereich des vertikalen Durchbruchs an den dem Implantat zugewandten Knochenoberflächen der Wirbel einführen. Die den vertikalen Durchbruch umgebenden Teile des Implantats liegen dann gegen Hartknorpelgewebe an, während vor allem das freigelegte Weichknorpelgewebe neues Knochengewebe bildet, das in den horizontalen Durchbruch eindringen kann und schließlich zur Verbindung der beiden an die Implantate 16, 16' angrenzenden Wirbel durch Knochengewebe führt. Auch durch die horizontalen Durchbrüche 9 kann neu gebildetes Knochengewebe dringen, so dass das Implantat weitgehend in die Wirbel verbindendes Knochengewebe eingebettet ist.

[0033] Die Zahnung 14 sorgt für eine Arretierung der Implantate 16, 16' zwischen den Wirbeln der Wirbelsäule 15, indem die Zähne der Zahnung 14 in das Hartknorpelgewebe eindringen. Die Zahnung 14 ist in Einführungsrichtung der Implantate gesehen in der ersten

Hälfte an der der Außenseite der Wirbelsäule 15 zugewandten Seite des Implantats angeordnet und liegt damit weit vom Nervenstrang der Wirbelsäule und weit von deren Hauptbelastungsachse entfernt. Durch das Eindringen der Zähne in das Knochengewebe kann es daher weder zu einer Beeinträchtigung von Nervenbahnen noch der Belastbarkeit der Wirbelsäule kommen.

[0034] Ein besonderer Vorteil der beschriebenen Implantate 16,16' liegt in ihrer Anpassung an die Form der den Implantaten zugewandten Oberfläche der miteinander zu verbindenden Wirbel. Dieser Form wird zum einen dadurch Rechnung getragen, dass das Implantat bei 7 ein Maximum der Höhe aufweisen. Dieses Maximum entspricht einem Maximum der Tiefe der Wirbeloberflächen an der betreffenden Stelle. Quer zur Einführungsrichtung nimmt die Tiefe der Wirbeloberfläche zu den Seiten hin ab. Dem trägt die Abnahme der Implantathöhe von der Längsseite 5 zur Längsseite 6 hin Rechnung.

[0035] Durch die weitgehende Formanpassung des Implantats an die Oberfläche des Wirbelkörpers verringert sich die Beanspruchung der miteinander zu verbindenden Wirbel durch das Implantat. Ferner trägt diese Formanpassung zur Lagestabilität des Implantats zwischen den Wirbeln bei. Beide Faktoren fördern letztlich ein schnelles Wachstum des die Wirbel miteinander verbindenden Knochengewebes und damit den Heilungsprozeß nach einer Bandscheibenresektion. Die Anforderungen an die Festigkeit von während des Verbindungsgewebewachstums erforderlicher Stützeinrichtungen verringern sich.

[0036] In dem gezeigten Ausführungsbeispiel ist die Implantathöhe an den Stirnenden 3 und 4 gleich groß. Abweichend hiervon könnte die Höhe am Stirnende 4 größer als am Stirnende 3 sein, so dass sich ohne den Anstieg und Abfall der Implantathöhe zwischen den Stirnenden die Gesamtform eines stumpfen Keils ergäbe. Solche in ihrer Grundform keilförmigen Implantate kommen vor allem für den unteren lumbalen Bereich der Wirbelsäule in Betracht, wo die Wirbel im Normalfall zueinander geneigt sind.

[0037] Anstelle zweier, in einem Wirbelzwischenraum nebeneinander anzuordnender solcher Implantate ließe sich auch ein aus den beiden Implantaten zusammengesetztes, einstückiges Implantat verwenden, das zu den Seitenrändern dachartig abfällt. Hierbei käme jedoch nur eine Implantation von der Vorderseite der Wirbelsäule her in Betracht.

[0038] Anhand der in die Durchgangsbohrungen 12 und 13 eingeführten Metallstifte lässt sich im Röntgenbild genau die Lage der Implantate und damit ihre ordnungsgemäße Implantation überprüfen.

[0039] Bei dem verwendeten Kunststoff Polyetheretherketon (PEEK) handelt es sich um ein hoch belastbares Material, das gegenüber metallischen Werkstoffen zudem den Vorteil hat, ähnlich nachgiebig wie Knochengewebe zu sein und sich daher problemloser als Metall in das Knochengewebe einfügt.

[0040] Je nach Größe und Verwendung innerhalb der Wirbelsäule kann das Implantat variierende Abmessungen aufweisen, wobei insbesondere unterschiedliche Keilwinkel und unterschiedliche Maximalhöhen in Betracht kommen.

[0041] Infolge der erforderlichen Variantenvielfalt werden die benötigten Stückzahlen von Implantaten mit gleichen Abmessungen gering bleiben, so dass gegenüber dem zur Herstellung des Implantats durchaus anwendbaren Spritzgussverfahren einer Zerspanungsbearbeitung der Vorzug zu geben ist, wobei Mischformen der Bearbeitung unter weitgehender Vorfertigung durch Spritzgießen denkbar sind.

Patentansprüche

1. Implantat (16) für die Anordnung zwischen Wirbeln der Wirbelsäule (15), **gekennzeichnet durch** eine Formanpassung des Implantats (16) an eine Vertiefung in den dem Implantat (16) zugewandten Wirbeloberflächen (17).
2. Implantat nach Anspruch 1, **dadurch gekennzeichnet, dass** in Richtung von der Vorderseite zur Rückseite der Wirbelsäule (15) die Höhe des Implantats (16) bis zu einem Maximum (7) ansteigt und wieder abnimmt.
3. Implantat nach Anspruch 2, **dadurch gekennzeichnet, dass** das Maximum (7) in Richtung von der Vorderseite der Wirbelsäule zur Rückseite gesehen im letzten Drittel der Implantatlänge liegt.
4. Implantat nach einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet, dass** in Richtung senkrecht zu einer die Wirbelsäule (15) von vorn nach hinten durchstoßenden Mittelachse die Höhe des Implantats (16) zu der Mittelachse hin ansteigt.
5. Implantat nach einem der Ansprüche 1 bis 4, **dadurch gekennzeichnet, dass** das Implantat (16) zu einer die Wirbelsäulenlängsachse senkrecht schneidenden Ebene symmetrisch ausgebildet ist.
6. Implantat nach einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet, dass** das Implantat (16,16') zur Anordnung in einem Halbraum des Zwischenraums zwischen den Wirbeln gemeinsam mit einem zu dem Implantat (16) spiegelsymmetrischen solchen Implantat (16') vorgesehen ist.
7. Implantat nach einem der Ansprüche 1 bis 6,

dadurch gekennzeichnet,

dass das Implantat (16) Vorsprünge (14) für die Arretierung am Knochengewebe der Wirbel aufweist.

8. Implantat nach einem der Ansprüche 1 bis 7, 5
dadurch gekennzeichnet,
dass eine in Implantationsrichtung vordere Stirnfläche (3) des Implantats (16) nach vorn ausgewölbt ist. 10
9. Implantat nach einem der Ansprüche 1 bis 8, 15
dadurch gekennzeichnet,
dass das Implantat (16) in der Art eines Käfigs hohl mit Wanddurchbrüchen (9,10) ausgebildet ist. 20
10. Implantat nach einem der Ansprüche 1 bis 9, 25
dadurch gekennzeichnet,
dass das Implantat (16) in der Draufsicht rahmenartig mit einem zur Ober- und Unterseite des Implantats öffnenden Durchbruch (8) als Rahmenöffnung ausgebildet ist. 30
11. Implantat nach einem der Ansprüche 1 bis 10, 35
dadurch gekennzeichnet,
dass das Implantat einen Kunststoff, vorzugsweise PEEK, aufweist. 40

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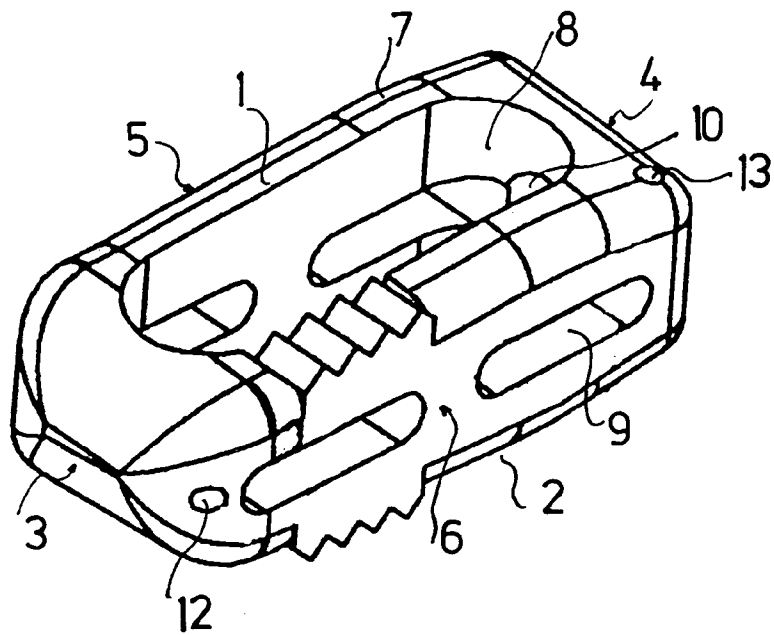


FIG.1

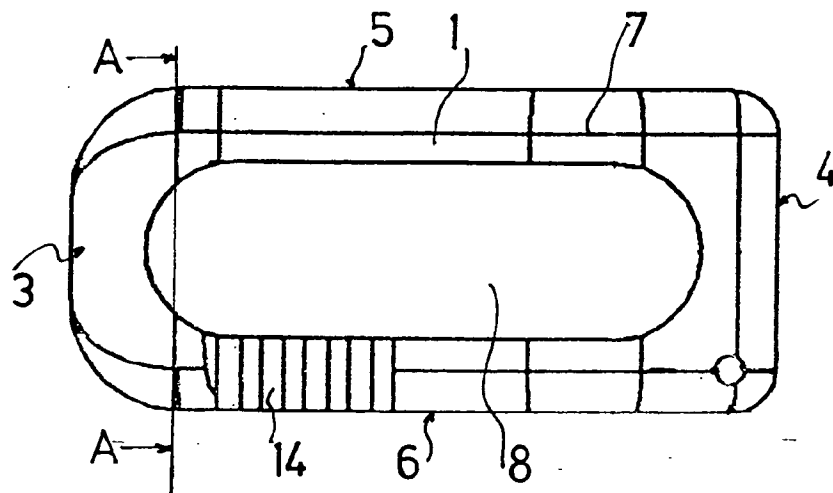


FIG.2

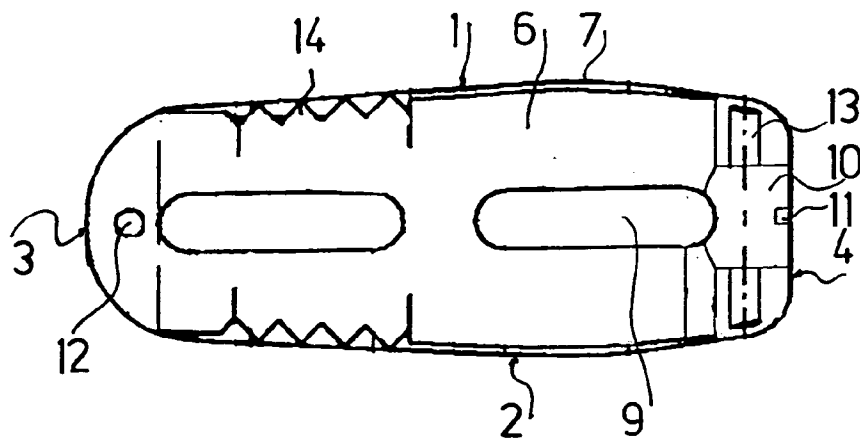


FIG. 3

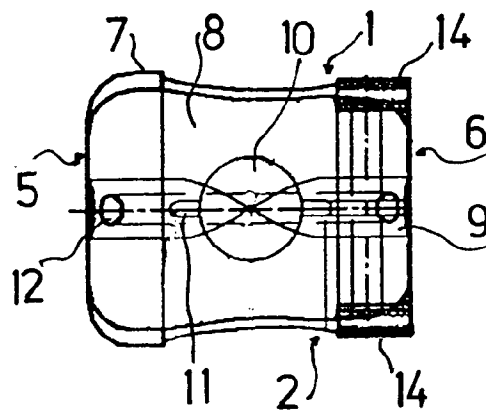


FIG. 4

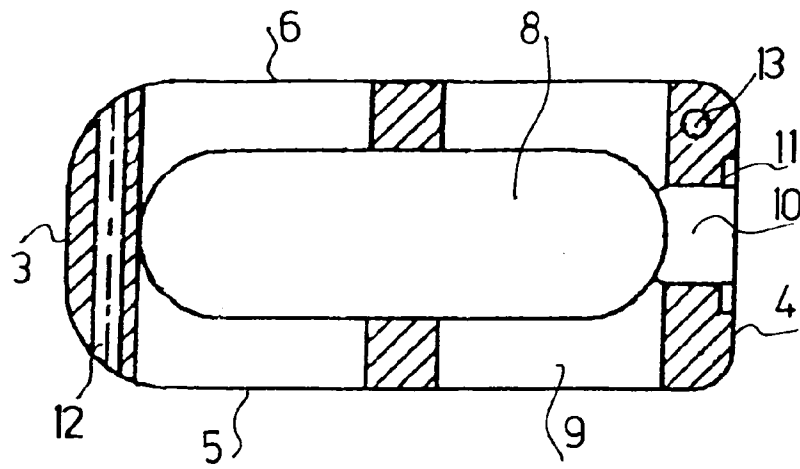


FIG. 5

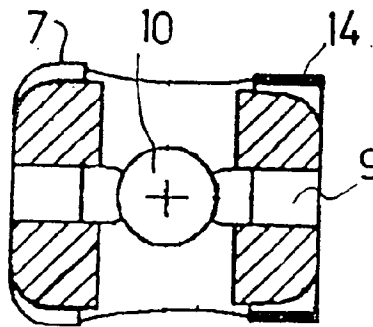


FIG. 6

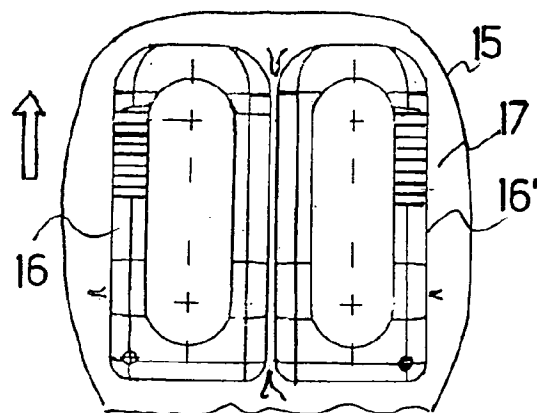


FIG. 7



Europäisches
Patentamt

EUROPÄISCHER RECHERCHENBERICHT

Nummer der Anmeldung
EP 03 02 1884

EINSCHLÄGIGE DOKUMENTE			
Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int.Cl.7)
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Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt			
Recherchenort BERLIN		Abschlußdatum der Recherche 23. Februar 2004	Prüfer Stach, R
KATEGORIE DER GENANNTEN DOKUMENTE X : von besonderer Bedeutung allein betrachtet Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie A : technologischer Hintergrund O : mündliche Offenbarung P : Zwischenliteratur T : der Erfindung zugrunde liegende Theorien oder Grundsätze E : älteres Patentdokument, das jedoch erst am oder nach dem Anmeldedatum veröffentlicht worden ist D : in der Anmeldung angeführtes Dokument L : aus anderen Gründen angeführtes Dokument & : Mitglied der gleichen Patentfamilie, übereinstimmendes Dokument			

EPO FORM 1503 03 82 (P04C03)

**ANHANG ZUM EUROPÄISCHEN RECHERCHENBERICHT
ÜBER DIE EUROPÄISCHE PATENTANMELDUNG NR.**

EP 03 02 1884

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Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am
Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

23-02-2004

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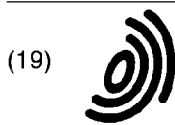
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Für nähere Einzelheiten zu diesem Anhang : siehe Amtsblatt des Europäischen Patentamts, Nr.12/82



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Office européen des brevets



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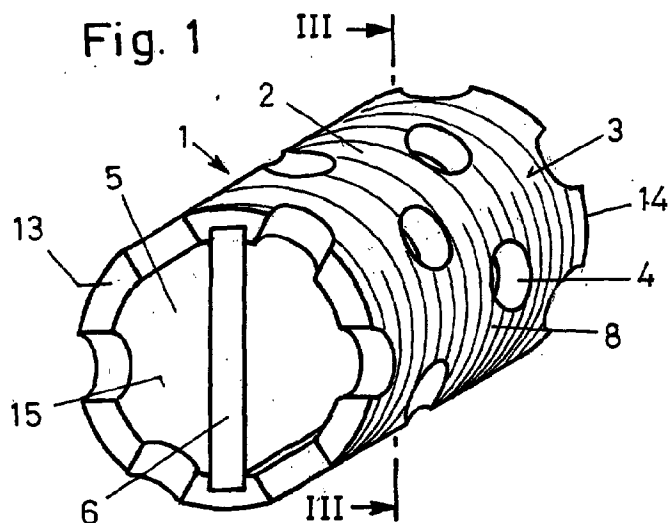
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(54) **Cylindrical fiber reinforced implant**

(57) The cylindrical fiber reinforced implant (1) is designed to be inserted between two adjacent vertebrae. The implant having an outer wall (2) with a general cylindrical or oval shape and preferably an open volume for bone filling. Said wall (2) having reinforcing fibers (12,17) which at least in part are oriented in a first direc-

tion. A support (6) extending within said volume having reinforcing fibers (10,11) which are at least in part oriented in a second direction, said first and said second directions are different. Preferably the fibers (12,17) of the outer wall (2) are at least partly concentrically oriented. The support (6) is preferably a separately formed part, that is inserted into the outer wall.



Description

[0001] The present invention relates to a three-dimensional fiber reinforced implant, particularly a vertebral cage designed to be inserted between two adjacent vertebra according to the preamble of claim 1.

[0002] Fiber reinforced implants are well known. US 5,429,863 for example discloses a vertebral implant cage, that is fabricated from a block, which is a fiber reinforced composite structure. Carbon fibers are located in every part of the block and randomly interlocked. The cage may have the shape of a cylindrical rod and is provided with cavities which are filled with bone material and is designed to be inserted between adjacent vertebrae.

[0003] US 5,906,616 discloses a conically-shaped fusion cage provided with a thread formed as a part of an external conical surface. Apertures provide for bone growth between the engaged vertical bone and bone material packed within the cage.

[0004] US 5,968,098 discloses a fusion cage having a generally elliptical cross-section. It includes an entry end portion, a trailing end portion and a thread as a part of an external conical surface. The cage is preloaded with bone material and inserted into the desired surgical location with well known surgical instruments.

[0005] A fusion cage formed of radiolucent material is also disclosed in EP-A- 0 307 241. The cage has a roughened outer surface for receiving bone in-growth and end faces with means securing it on a tool for insertion on the desired site of the vertebrae.

[0006] The role of a vertebral implant is to stabilize a vertebral segment and to bear load while the surrounding bone consolidates, taking over the mechanical function with a viable bone fusion. On one hand the implant must be robust enough to bear rotation at insertion, and axial load, sheer and fatigue during weight bearing. On the other, the implant must provide enough space for bone graft to grow through or around the device. Thus cage designers are faced with a trade off what makes the implant bear load, and the bone ports which must carry enough bone tissue required for bone consolidation. Furthermore, it has been postulated that stress shielding in an implant may prevent fusion of viable bone through the implant, and strength and stiffness should be as close to the surrounding bone tissue as possible.

[0007] Several materials are used for inter-body cages and most commonly are Titanium Alloy, PEEK as well as carbon composite. Titanium, while certainly strong enough for the application, has the disadvantage of being a radiographically opaque, making it impossible to visualize if bone has grown through the cage with standard x-ray. It is also known that titanium also produces artifacts for other radiographic examinations such as C.T. or MRI.

[0008] It is an objective of the present invention to provide a three-dimensional fiber reinforced implant, that is radiolucent and provides increased mechanical per-

formance, while at the same time maximizes the space for bone graft.

[0009] Cylindrical implants have the advantage of easier insertion. Both the reaming and interspace preparation and cage insertion are performed with a twisting motion.

[0010] Square or rectangular cages, on the other hand, can be more easily reinforced with vertical struts. To prevent collapse of cylindrical cages, wall thickness is increased that reduces cavity size preventing the formation of viable bone. The invention described herein, through the use of selectively orienting the fibers in the various cage components has contributed a cage resistant to collapse and rotation, but preserves an ample cavity for bone.

[0011] The implant according to the present invention is provided with a support extending within the outer wall and has reinforcing fibers which are at least in part oriented in a direction which is different to the orientation of fibers embedded into the outer wall. The additional orientation of the fibers within the support prevents a deformation of the implant to where the fibers of the outer wall are bent beyond the point of failure. Deformation beyond the point of breakage is prevented in axial load, bending, rotation, impact and shear.

[0012] The support is preferably a separately formed part, that is inserted into the outer wall, but can be also a part of the outer wall.

[0013] Other advantages and features of the present invention will be apparent to those skilled in the art after reading the following specification with reference to the accompanying drawings.

Fig. 1 is a schematic perspective view of a fiber reinforced cage of this invention,

Fig. 2 is a schematic perspective view of the cage according to Fig. 1 wherein the support is partly withdrawn from the outer wall,

Fig. 3 is a section along line III-III of Fig. 1,

Fig. 4 is a schematic perspective view of a part of the support as seen in Fig. 3,

Fig. 5 is a plan view of a further embodiment of the invention,

Fig. 6 is a cross-section along line VI-VI of Fig. 5,

Fig. 7 is a schematic perspective view of a cage according to a further embodiment of the invention,

Fig. 8 is a schematic perspective view of a cage according to a further embodiment of the invention and

Fig. 9 illustrates the orientation of the fibers in the cage according to Fig. 8.

[0014] Referring now to the drawings wherein like numerals indicate like parts, the cage of this invention is depicted by the numeral 1. The cage 1 has a pair of front surfaces 13 and 14, an outer surface 3 and an inner surface 15. A cylindrical outer wall 2 has several perforations or ports 4 which connect the outer surface with the cavity and which enable fusion of bone through the cage. Further, the outer surface 3 is provided with a thread 8. The cage is packed with bone chips or bone substitute not shown in the drawing.

[0015] A support 6 having the shape of a plate is inserted into grooves 9 of the cavity 5. The support 6 is inserted in the longitudinal direction of the outer wall 2, as indicated with arrow 7. The outer wall 2 as well as the support are made from carbon fiber composite. Fibers 10 and 11 are preferably oblique to the longitudinal direction but may also be perpendicular to the longitudinal direction. In Fig. 4 the longitudinal direction is indicated with line 16. Fibers 10 and 11 within the support have preferably two directions of orientation as shown in Fig. 4 and can run along the entire length of the support 6. The matrix of the support 6 as well as the outer wall 2 are made from PEEK or PEKEKK preferably from commercially available Osta-PEK®.

[0016] Long fibers in the support 6 can extend completely along the axis of the part that provides optimal strength and regularity of the mechanical properties of the implant. The same is there on the concentric fibers. These can wind up around the cylinder several times within the part and opposing fibers can cross the entire part in a different direction. Cross direction holds the part together and allowing it to resist loads that will be subject to the implant from different directions. The difference in mechanical properties between short carbon fiber composite and long fiber composite in a controlled orientation can be compared to particle board and the structure in well carpentered oak. Particle board is held together by glue, while the oak structure uses fabric orientation of wood to oppose the forces and subjected upon the structure.

[0017] Fibers 12 and 17 within the outer wall 2 are preferably concentrically and/or longitudinally oriented. The fibers 12 are preferably long fibers and may run along the entire circumference of the outer wall. The fibers 17 are as well preferably long fibers and may run in the longitudinal direction along the entire length. It is an important aspect of the invention, that the fibers 10 and 11 of the support 6 and the fibers 12 of the outer wall 2 have different orientations. The additional orientation of the fibers 10 and 11 prevents deformation of the cage 1 to where the fibers 12 are bent beyond the point of failure. The fibers 12 need not always be concentrically oriented and could be also parallel to the longitudinal direction 16. Furthermore, part of the fibers could be concentrically oriented and another part of the fibers

could be parallel to the longitudinal direction 16.

[0018] Figures 5 and 6 disclose a cage 20 having a wall 24 with a generally round cross-section and a support 23 integrally connected to the wall 24. The cage 20 is formed of radiolucent material and contains imbedded long reinforcing fibers 21 and 22. The fibers 21 of the wall 24 are generally concentrically oriented or parallel to the longitudinal direction 16. The fibers 22 of the support 6 have at least one additional orientation, that is preferably oblique to the longitudinal direction 16. As shown in Fig. 6, Fibers 22a may have an orientation different to that of fibers 22b. Fibers 22 could be also perpendicular to the longitudinal direction 16.

[0019] Fig. 7 shows a cage 30, that is also formed of radiolucent material and contains fibers 31 and 37 with different orientations. The cage is made of two parts, an outer wall 39 having a generally round or oval cross-section and a box-like support 33, that slides in the wall 39 like a drawer. Apertures 34 within the support 33 provide for bone growth and can be preloaded with bone material. The wall 39 can also have not shown apertures for bone growth and a thread as a part of an external surface 36. The fibers 31 are preferably oriented in concentric circles whereas the fibers 37 have an additional orientation, for example perpendicular to the longitudinal direction 16.

[0020] Fig. 8 shows a cage 40, that is also made of two parts, an outer wall 42 and a support 43, that is an insert and contains fibers 45 and 46 having different orientations. The outer wall 42 contains concentrically oriented fibers 41 and has a generally round or oval cross-section. The support 43 is provided with apertures 44 which can be preloaded with bone material and slides in the outer wall 42 like a drawer, as indicated with arrow 48. The fibers 45 and 46 are preferably long carbon fibers and have different orientations to each other and to the fibers 41. The fibers 45 are vertically oriented and the fibers 46 are horizontally oriented and parallel to the longitudinal direction 16. In Fig. 9 the orientations of the fibers 41, 45 and 46 are schematically indicated with arrows 47 to 49.

Claims

1. Three-dimensional fiber reinforced implant, particularly a vertebral cage designed to be inserted between two adjacent vertebrae, the implant having an outer wall with a general cylindrical or oval shape and preferably an open volume for bone filling, said wall having reinforcing fibers which at least in part are oriented in a first direction, a support extending within said volume having reinforcing fibers which are at least in part oriented in a second direction, said first and said second directions are different.
2. Implant according to claim 1, wherein the fibers of the outer wall are at least partly concentrically ori-

ented.

3. Implant according to claim 1 or 2, wherein the fibers of the outer wall are at least partly parallel oriented. 5
4. Implant according to claim 1 or 2, wherein the fibers of the support are at least partly parallel oriented.
5. Implant according to any of the claims 1 to 4, wherein the support is a separate insert. 10
6. Implant according to any of the claims 1 to 5, wherein the support is a strut.
7. Implant according to any of the claims 1 to 6, wherein the support is like a drawer inserted within said volume. 15
8. Implant according to claim 7, wherein the support is like a round drawer. 20
9. Implant according to any of the claims 1 to 8, wherein the fibers of said outer wall are at least partly concentrically and the fibers of the support are at least partly longitudinally oriented. 25

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Fig. 1

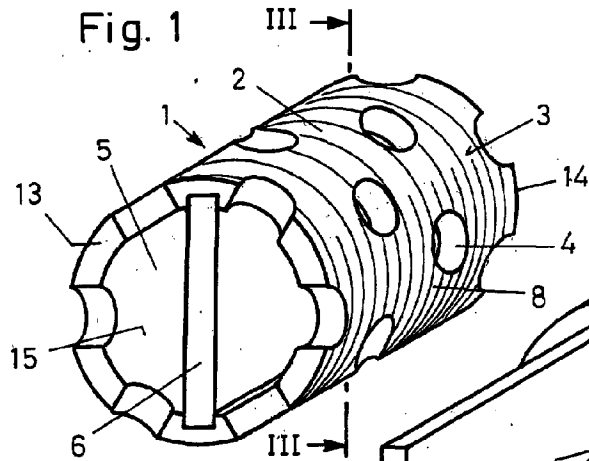


Fig. 2

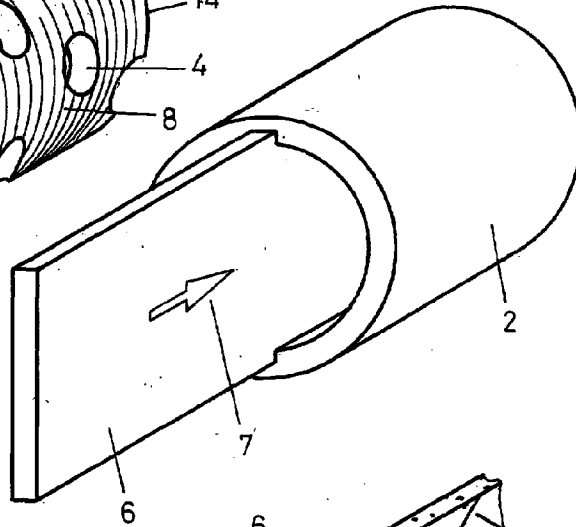


Fig. 3

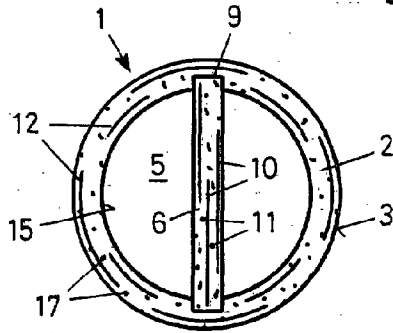


Fig. 4

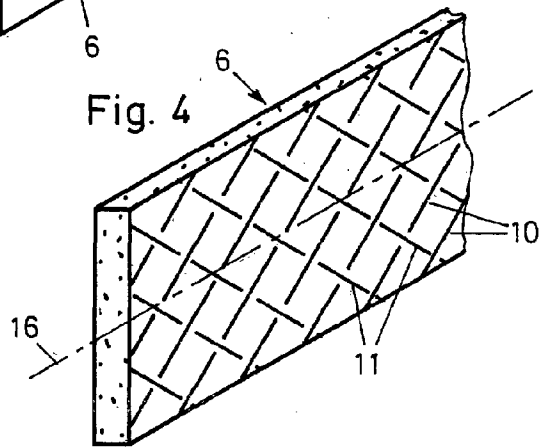


Fig. 5

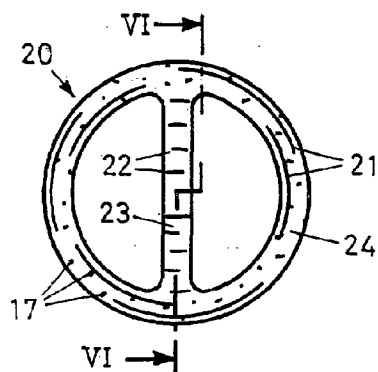


Fig. 6

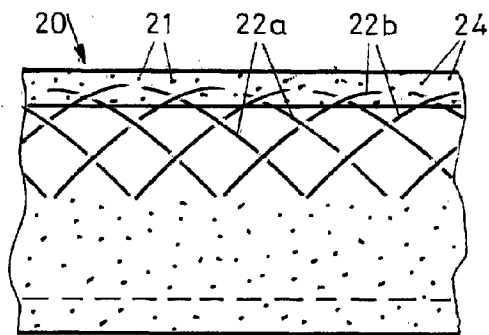


Fig. 7

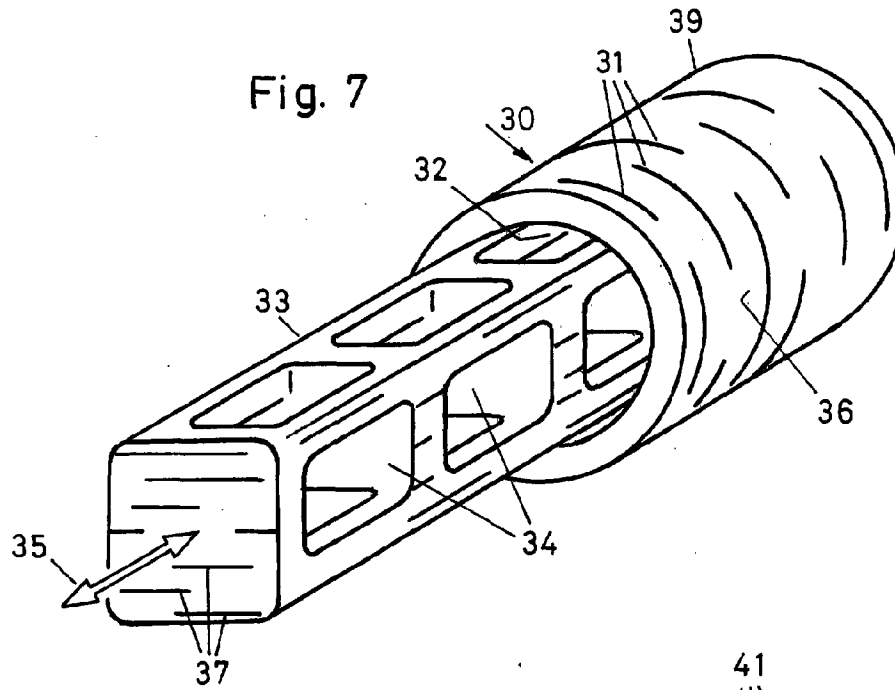


Fig. 8

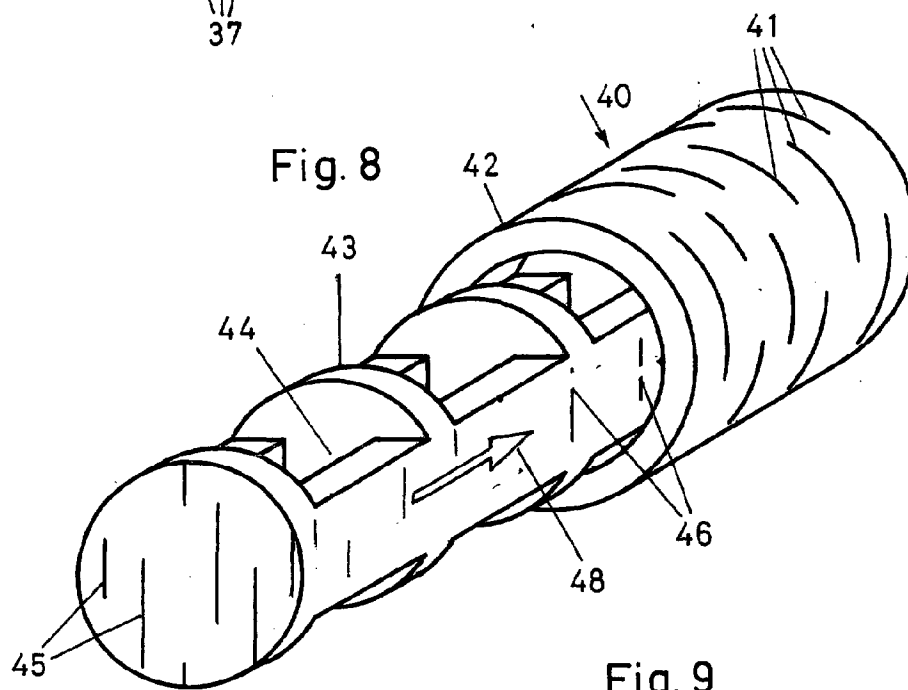
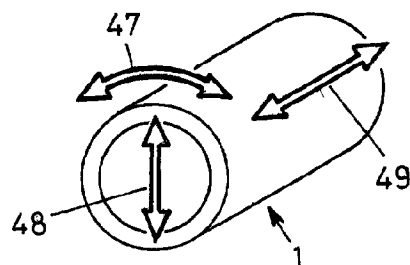


Fig. 9





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 02 40 6104

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The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
BERLIN		22 May 2003	Stach, R
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<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p>			
<p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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ON EUROPEAN PATENT APPLICATION NO.**

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The members are as contained in the European Patent Office EDP file on
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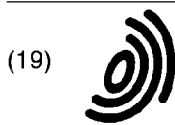
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IE IT LI LU MC NL PT SE SI SK TR
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AL LT LV MK RO

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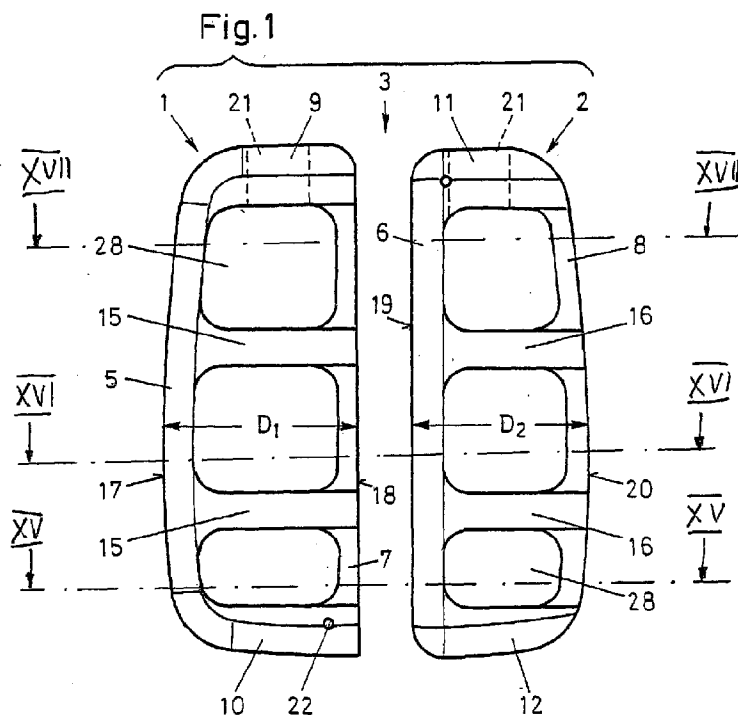
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(54) **A pair of lumbar interbody implants and method of fusing together adjoining vertebrae bodies**

(57) The pair of lumbar interbody implants is designed to be pushed laterally in a space between adjacent vertebrae for replacing the disc between these vertebrae. Each implant comprises a first and a second sagittal wall and an anterior wall at one end and a pos-

terior wall at the other end. The two implants are asymmetric to each other and are therefore more appropriate for the trans-foraminal lumbar interbody fusion. Preferably a first implant has a first sagittal wall with an outer surface that is curved and a second sagittal wall that is essentially plane.



Description

[0001] The invention relates to a pair of lumbar interbody implants designed to be pushed laterally in the disc space between adjacent vertebrae for a spinal, interbody fusion.

[0002] WO 00/44318 (Commarmond) discloses an interbody implant being in the form of a cage. It has a top edge and a bottom edge to provide at least a retaining ridge. The cage enables posterior approach insertion in the space between adjacent vertebrae and a lateral shift to a locking position in the intervertebral space. The retaining ridge prevents the cage from slipping in a side-ways or lateral direction.

[0003] US 5,607,424 (Tropiano) discloses a lumbar interbody cage having upper and lower surfaces that provide a more anatomical contact with the abutting surfaces of the vertebral interspace.

[0004] Debilitating back and leg pain is one of industrialized society's most pervasive source of infirmity. In spite of more and more sophisticated technology, the exact causes of leg and back pain are not exactly known for each individual. However, pain symptoms are often associated with the degeneration of specific structures in the spine, which can become painfully unstable, thought to cause back pain, or compress a neural structure, which are believed to be a source of leg pain. In most cases, a spinal fusion is designed to decompress painful nerve root impingement and to eliminate painful movement by fusing two or more vertebrae together in a controlled and aligned fashion.

[0005] To those familiar with the art, the spine being is thought to be composed of many motion segments, each one consisting of a weight bearing disc, two adjacent vertebral bodies and their respective pedicles, as well as the posterior facet joints, the lamina and spinous and transverse processes. The disc's primary role is to bear weight, and allow a few degrees of bending and rotation at each motion segment. The bilateral posterior facet joints have a stabilizing role, preventing dangerous translation of two vertebral bodies and too much rotation of the motion segment, which could damage neural structures.

[0006] The dural sac runs adjacent to the posterior aspect of the vertebral body. It contains nerves, which extend to various parts of the body. The surrounding structures of the vertebral column form the spinal canal and protect the dura from trauma and allow motion. At each motion segment, the spinal canal is composed of the posterior wall of the disc, the pedicles, the vertebral body and the posterior elements. It should be noted, that the spinal canal is quite vascular and when retracted for a surgical procedure, can cause excessive bleeding. At each motion segment, the exiting nerve roots pass out bilaterally, from the dura within the spinal canal, through corresponding neural foramen, which are formed bilaterally by the pedicle, the facet joints and posterior disc.

[0007] Degeneration of a spinal segment is marked

by a cascade of events, where the disc develops small tears, possibly resulting in a painful and nerve compressing herniations. This can be caused by any combination of age, trauma or disease. The disc gradually will collapse like a deflated tire and then bulge into the vertebral canal while foramen close upon the nerve roots, causing compression, which in some patients is a great source of pain felt in the legs.

[0008] As the degenerative process advances, the facets joints and disc can create hypertrophic bone growths, creating bone spurs, which can further compress the neural structures, and cause additional pain, neurological abnormalities such as partial loss of sensation or ability to move.

[0009] This cascade of events can occur in one or many motion segments of the spine, each with varying degrees of degeneration and presumed source of pain. All spines show some degrees of this process, as a person ages. Some patients find the various phases in these events to be intolerably painful and incapacitating, due to what can be termed neural compression and segmental instability. Yet other patients, in spite of such spinal degeneration, continue to function. Where several motion segments show degeneration, some segments can be the source of pain, while others not. The reasons for these seemingly contradictory observations are not entirely understood. This complicates the surgeon's choice of which motion segment to treat to reduce the patient's pain and return him to function.

[0010] Certain suffering patients, and certain painfully degenerative spinal motion segments, can be improved with a procedure called a spinal fusion. The spine surgeon is thus challenged to determine which motion segment might be the source of the patient's predominate pain, and which patient might benefit from the operation. The surgeon's goal will be to decompress the painful impinging structures on the nerves and then to stabilize one or several motion segments, often using implants, including cages, which are the subject of this invention. The implants hold the operated motion segment in proper alignment so that two or more vertebral bones may grow together over several months, forming one continuous bone. This blocks painful motion, leaving the formerly impinged nerves decompressed. Because the spine is comprised of many motion segments, like the links in a chain, normal motion of the spine is still possible due the mobility of the segments above and below the fusion. In fact, because all human spines are settling as a patient ages, some without pain, it is thought a spinal fusion is a controlled version of a natural process, in a manner that will avoid pain.

[0011] There are several types of implants used to stabilize a motion segment for spinal fusions. Interbody cages are used between the vertebral bodies, to bear weight where the disc was removed, between the vertebral bodies. Such cages are most often filled with an osteoinductive material, in most cases the patients own bone, or more recently a bone substitute, which promote

bone cell growth through and around the cage to the adjacent vertebrae to become fused. Where the posterior structures are decompressed and destabilized, cages are often associated with additional anchor and stabilizing mechanisms such as pedicle screws, laminar hooks, plates and rods, which together with the cages, serve as sort of a scaffolding that holds the vertebral segments in a stable alignment while bony fusion occurs and the vertebra grow together. At this point, the implants loose their stabilizing role, which is taken over by viable bone. The assembly of decompressed motion segment, cages and associated implant, along with an osteoinductive material is what practitioners of spinal fusion call a "fusion construct."

[0012] Thus each spinal fusion has the goal to eradicate the source of pain, by stabilizing what is painfully mobile, and decompressing what painfully compresses a nerve. The surgeon achieves this by resection of the compressive structures, stabilizing the motion segment in alignment with implants, and the proper management of bone cell biology so that the motion segment will grow together over several months into one continuous bone. During the formation of healthy bone between the vertebrae of a bone segment, there is a race between the mechanical fatigue resistance of the implants and weight bearing bone. The goal is for the bone to take over the weight-bearing role of the construct after several months. If fusion does not occur, over time the implants will break and fail. After a successful fusion, and although implants no longer have a stabilizing or weight bearing role, spinal implants are seldom removed, as it felt that the additional risks of infection or additional trauma from another surgery would out weigh the possible benefit of removing the implant. Therefore most spinal implants remain in the body for the rest of the patient's life.

[0013] When a spine surgeon wishes to perform a spinal fusion with implants, he has several surgical approaches and techniques to build a fusion construct, each with its advantages, risks and shortcomings. From a general sense, the spine surgeon wishing to perform a spinal fusion is faced with a dilemma. On one hand to generously expose soft tissue and bone to allow proper neural decompression, and implant insertion, with proper segmental alignment and correction. On the other hand, to avoid excessive trauma from the approach. Excessive dissection of a surgical approach, makes the procedure easier for the surgeon, but destroys viable tissue, leading to damage of the surrounding muscle groups, which the body later uses to keep the entire spine in dynamic equilibrium. Furthermore, decompression of the posterior elements, in particular the facet joints, while relieving nerve impingement, can further destabilize the spinal segment to be fused, not allow the fusing bone graft to properly vascularize and reduce the probability of the vertebrae of spinal construct to grow together. Therefore, each of the various techniques available to the surgeon, represent a compromise be-

tween the goals of sufficient dissection and decompression, and the need to inflict minimal trauma or instability on the segment to be fused.

[0014] Interbody cages are valuable because they place an immobilizing support and fusing bone graft material, where most of the natural load upon the spine can be found, the interspace. Because the cage's role is to bear weight where the disc once was, it is thought that more disc space covered with a cage and bone graft and the better the fit between surfaces of the cage and vertebrae, the more stable the resulting weight bearing fusion construct. A stable but not too rigid construct is desired to allow the bone cells to recognize weight bearing, which is required for the formation of healthy bone. Furthermore, the disc space must be filled as much as possible with bone cells and supporting surface of the cage. When the surgeon desires to place his cages from the posterior approach, usually because he must perform decompression at the same time within the canal, he must go around the dura and avoid trauma to the exiting nerve roots. As a maximum of disc space must be filled with the bone and cage construct the question from the posterior approach becomes, how to provide bi-lateral support avoiding the neural structures. Furthermore, some patients requiring a fusion have had a previous failed spinal surgery, such as a removal of a herniated disc. This leaves scar that is difficult to dissect from the surrounding neural tissues without damage.

[0015] Traditionally, spine surgeons use a bilateral, Posterior Lumbar Interbody Fusion (PLIF) technique. Here a portion of the lamina, and the interior of both facets are removed, so the cages may be placed bilaterally into disc space, to the left and right past the dural sac, leaving two bilateral cages within the interspace and a stable support where the disc once was. Because cage passage for this bilateral construct requires the partial dissection of both the facet joints, it destabilizes the motion segment. Therefore pedicle fixation is often used in conjunction with the PLIF procedure. This is quite satisfactory from a neurological and biomechanical, point of view. It allows full decompression of the offending pathology within the motion segment, and provides stable alignment and support with bilateral cages, bone graft in the interspace and pedicle fixation that replace the role of the resected facet joint. However this is accomplished at the cost of sever dissection of the muscle groups of the approach, and at times, a complex and risky passage through scar tissue on previously operated motion segments. These observations have lead surgeons to search for constructs and surgical approaches with the same biomechanical and neurological results, but with less destruction to the surrounding tissue.

[0016] The transforaminal approach and technique is disclosed in "Rivista die Neuroradiologia 12 (Suppl. 1): 107-110, 1999" by J. Commarmond and others, and is thought to be an alternative with some attractive qualities. This technique allows placement of bilateral cages, but dissects only one side of the paraspinous muscles,

one facet joint as opposed to two for a PLIF procedure. In the case of a PLTF procedure, a surgeon must dissect and disrupt two sides for bi-lateral placement of the cages. This is fine when both sides require dissection for treatment of the neural compression, but there are certain cases where degeneration and the resulting symptoms are thought to come predominantly from one side. Therefore the therapeutic requirements to decompress a facet joint concern one side and not the other.

[0017] Typically such patients complain of neurogenic pain predominantly from one side, and it is often with transforaminal approach that the facet joint of the spine can be removed only from the painful side to prepare placement of the cages. The healthier side is avoided and thus muscular, neuro and vascular tissue is preserved. For revision cases, previously operated cases, dangerously adhering scar tissue can be avoided. Thus the transforaminal procedure is unilateral in its approach and builds a bilateral construct described bellow. Decompression and tissue damage is made for reasons of pathology, and less the building of a stable construct.

Transforaminal Technique

[0018] Decompression is made from one side. The disc is exposed and its material is removed from one side. The goal at this moment is to eliminate cartilaginous tissue that will prevent formation of bone, and expose subcondral bone with good vascular supply for the bone graft, and to allow space for the first and second cage. A pathway for a pair of dissimilar cages is created laterally from an entry point just bellow the resected facet joint. Again this is usually the side where the most nerve root compression is located, or in the case of a second surgery such as a herniated disc, from the side where no scar tissue has been formed.

[0019] To allow insertion of the first and the second cage, disc space height restored using interspace spreaders. The far lateral cage is first pushed into the space. It is designed to go the furthest into the disc space laterally; its leading surface has a distraction and therefore decompression role of the contra lateral foramen. It is pushed part way laterally with an instrument and surfaces are designed for a lateral distraction of the interspace and anchoring once in place. The second cage is inserted through the same incision. Its has a surface that mates with the first cage, which helps push the first to its far lateral position.

[0020] The two cages are designed to help to restore the spine to its normal condition, that is restore disc space height, open the foramen to make a nerve decompressing passage, and provide proper lordosis. This unilateral posterior approach is especially suitable when nerve root impingement is purely unilateral, after a failed vertebral operation.

OBJECTIVE

[0021] An objective of this invention is to provide a pair of lumbar interbody implants which is more appropriate for the transforaminal lumbar interbody fusion technique.

SUMMARY OF THE INVENTION

[0022] In accordance with the invention, a pair of lumbar interbody implants is provided designed to be pushed laterally in the disc space between adjacent vertebrae for spinal, interbody fusion.

[0023] Each implant comprises a first and a second sagittal wall, an anterior wall at one end and a posterior wall at the other end. The posterior wall has means to receive a positioning tool. The implants further comprise an upper surface and a bottom surface. The first and second sagittal walls each of which has an outer surface and top and bottom edge. The two implants are asymmetric to each other. The asymmetry of the two implants does not relate to minor differences such as different markers.

[0024] Each implant according to the invention is designed to perform a sequence of functions during insertion into the disc space. The requirements of each step of the operation are different, and therefore so are the first and the second implant.

[0025] According to a further embodiment of the invention the first implant has a rounded lateral side, which enters first. This helps to ease insertion and the implant to move laterally into disc space and restore the disc space height, opening a nerve root compressing foramina. This also can restore the balance of the spinal segment by providing lordosis of the segment.

[0026] According to a further embodiment of the invention the second implant has rounded edges on a far lateral side. The near lateral side is flat with pronounced comers that engage in the bony end-plate when the patient stands or ambulates. This feature prevents undesirable cage migration, which can prevent vascularization of the bone graft and exclude fusion, or displace to create compression on a nerve structure with its associated complications.

[0027] According to a further embodiment of the invention, the far lateral side of the second implant is flat and mates with the first implant in order to push the first cage further laterally and to better restore the disc space height, which again opens the far lateral foramen and therefore releases pressure on the nerve roots. It also provides better support under axial load when the patient is ambulating and weight heaving.

[0028] According to a further embodiment, at least one of the implants has upward struts designed to make insertion of the implant into the disc space easier and to prevent anterior as well as posterior migration of the inserted implant.

[0029] According to a further embodiment of the in-

vention at least one of the implants is shaped with the posterior portion that is not as high as the anterior portion providing lordosis.

[0030] According to a further embodiment of the invention the second implant is smaller than the first implant.

[0031] Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

- Figure 1 is a top view of a pair of implants of this invention,
- Figure 2 is a transverse section of vertebrae interspace with both implants in situ,
- Figure 3 is a perspective view of the first implant of this invention,
- Figure 4 is a plane view of the implant of Figure 3, from the near lateral side,
- Figure 5 is another plane view of the implant of Figure 3, as will be seen from the coronar view, and showing the preferred orientation of the carbon fibers,
- Figure 6 is another plane view of the implant of Figure 3,
- Figure 7 is a perspective view of the second implant of this invention
- Figure 8 is a plane view of the second implant of Figure 7,
- Figure 9 is another plane view of the second implant of Figure 7,
- Figure 10 is another plane view of the second implant of Figure 8,
- Figure 11 is a diagrammatic section of a vertebral interspace of a vertebrae column showing the insertion of the first implant,
- Figure 12 is a view similar to Figure 11 illustrating the insertion of the second implant,
- Figure 13 is a view similar to Figure 11 showing the placement of the first implant on the counterlateral side of the disc space,
- Figure 14 is a view similar to Figure 11 showing both implants in situ
- Figure 15 is a cross-section along line XV-XV of Figure 1,
- Figure 16 is a cross-section along line XVI-XVI of Figure 1,
- Figure 17 is a cross-section along line XVII-XVI of Figure 1.

[0032] In Figure 1 the reference number 3 refers to a first implant 1 and a second implant 2. The first implant 1 and the second implant 2 are in the form of a cage as shown in Figures 3 and 7. The implants 1 and 2 have a hollow space 28 which is filled with bone graft material, not shown, that will grow out and into the bone tissue of the adjoining vertebrae 4. The implants 1 and 2 are pref-

erably made of radiolucent carbon fiber reinforced polymers or of another rigid biologically acceptable and preferably radiolucent material.

[0033] The first implant 1, as shown in Figures 1 to 7, has a first saggital wall 5 and a second saggital wall 7. The first saggital wall 5 has a curved outer surface 17 and the second saggital wall 7 a surface 18 that is essentially plane. A posterior wall 9 is provided with a threaded hole 21 extending through the wall 9 for receiving a threaded, positioning tool 38. As illustrated in Figure 3, the posterior wall 9 has rounded edges 23, 24, 29 and 42. The rounded edge 23 leads to an outer plane surface 18 of the second saggital wall 7 and the rounded edge 24 to an outer curved surface of the first saggital wall 5. The rounded edge 29 leads to a bottom surface 14 and the rounded edge 42 to a top surface 13.

[0034] An anterior wall 10 is essentially parallel and in space to the posterior wall 9. The wall has a sharp edge 26 and a rounded edge 27. The sharp edge 26 leads to the plane surface 18 and the rounded edge 27 to the curved outer surface 17, as shown in Figure 5 to 7.

[0035] Two upward strut plates 15 extend between the two saggital walls 5 and 7. These strut plates 15 have sharp edges 15a that are in the plane of the surface 18 and that are laterally protruding as shown in Figures 3 and 4. Adjoining the first saggital wall 5 outer surfaces 13a and 14a of the strut plates smoothly adjoin rounded edges 43 that go over the curved outer surface 17.

[0036] The second implant 2 is preferably made of the same material as the first implant 1 and is also provided with a hollow space 28 to be filled with bone graft material. A first saggital wall 6 and a second saggital wall 8 are in a spaced relationship with one another and essentially parallel to each other. The first saggital wall 6 has a plane lateral surface 19 and the second saggital wall 8 a curved lateral surface 20. A posterior wall 11 is provided with a threaded opening 21 extending through wall 11 for receiving a threaded, positioning tool 38. As shown in Figures 8 and 9, the posterior wall 11 has rounded edges 33, 35, 44, 45 and 21. The rounded edge 33 adjoins the plane surface 19 and the rounded edge 44 adjoins the curved surface 20. The rounded edge 35 adjoins a top surface 46 and the rounded edge 45 a bottom surface 47. As shown in Figures 15 to 17, the surfaces 46 and 47 of the implant 2 are parallel to each other. The surfaces 14 and 15 of the cage 1 are inclined as indicated with the dotted lines A und B (Fig. 17). The inclined surfaces 14 an 15 make the insertion of the first implant 1 easier.

[0037] An anterior wall 12 is essentially parallel to and in spaced relationship with the posterior wall 11. Wall 12 has rounded edges 34 and 37 that adjoin the plane surface 19, the curved surface 20, the top surface 46 or the bottom surface 47. The posterior wall 11 and the anterior wall 12 have rounded edges similar to edges 34 and 37.

[0038] The method of fusing adjoining vertebrae bodies according the present invention is illustrated in Figures 11 to 14. The method comprises clearance of the

intervertebral disc space and opening the neuroforamen on one side wherein the facet joint is resected and a canal C is opened. Preferably, the disc height can be partially restored by inserting a spreader. In Fig. 11 the left muscle M is not injured.

[0039] Into the canal C a first implant 1 is introduced with the help of a positioning tool 38 and then pushed laterally. The first implant 1 has the rounded side R lateral and is designed to go the furthest into the disc space laterally. It tends to restore the disc space like a wedge, which distracts the far lateral annulus and thus further opens the far lateral foramina, decompressing the nerve root.

[0040] When the first implant 1 is positioned as shown in Figure 12, a second implant is introduced in direction of arrow 40 through the same canal C with the help of a positioning tool 38. This second implant 2 has rounded edges R_2 on a far lateral side and a flat side F_2 , that mates with a flat side F of the first implant and pushed the first implant contralaterally into its final position as illustrated in Figure 13. The lateral force acting on the first implant is indicated with arrow 41. The upward strut plates 16 make the insertion of the second implant 2 into the disc space easier, like rails, but prevent anterior and posterior migration of the implant in its final position.

[0041] As already explained, the first and the second implants are asymmetric to each other. Especially the dimensions D_1 and D_2 as shown in Figure 1 are different. D_2 is preferably smaller. D_1 is for example 8 mm and D_2 7 mm. Each implant 1, 2 is designed for what it is to do during its part of insertion. The requirement of each step as shown in Figures 11 to 13 is different and therefore so is the implant.

[0042] Figure 14 shows the final position of the implants 1 and 2. The implants 1 and 2 can have the flat sides F and F_2 in contact with one another but can also spread from each other.

Claims

1. A pair of lumbar interbody implants designed to be pushed laterally in the disc space between adjacent vertebrae for spinal, interbody fusion wherein each implant comprises:

- a first and second saggital wall (5, 7; 6, 8);
- an anterior wall (10) at one end and a posterior wall (9, 11) at the other end;
- said posterior wall (9, 12) has means (21) to receive a positioning tool;
- an upper surface and a bottom surface;
- said first and second saggital walls each of which has an outer surface and top and bottom

edges, wherein

- the two implants are asymmetric to each other.

2. A pair of claim 1, wherein a first implant has a first saggital wall with an outer surface that is curved and a second saggital wall that is essentially plane.

3. A pair of claim 1, wherein at least one strut (15, 16) is extending between the two saggital walls.

4. A pair of claim 2, wherein a second implant has a first saggital wall with an outer surface that is curved and a second saggital wall that is essentially flat.

5. A pair of claim 3, wherein the distance between the outer surface of the first implant is larger than the distance between the two outer surfaces of the second implant.

6. A pair of claim 1, wherein at least one saggital wall of the first cage and one saggital wall of the second cage has a top and a bottom edge each of which is rounded.

7. A pair of claim 3, wherein the flat surfaces of the saggital walls are mating surfaces.

8. A pair of claim 1, wherein the implants being in the form of cages.

9. A pair of claim 1, wherein a first implant, that is to be inserted first into the disc space, has a rounded lateral side, which enters first.

10. A pair of claim 1, wherein the second cage that is to be inserted second into the disc space has rounded leading edges on a far lateral side.

11. A pair of claim 1, wherein at least one of the implants has upward struts designed to make insertion of the implants into the disc space easier, like rails, and to prevent anterior as well as posterior migration of inserted implant.

12. A pair of claim 1, wherein at least one of the implants is shaped with a posterior portion that is not as high as an anterior portion, providing lordosis.

13. A pair of claim 1, wherein the second implant that is to be inserted second into the disc space, is smaller than the first cage, wherein the height and the length of the two implants are essentially the same.

14. A method of fusing together adjoining vertebrae bodies with a disc space therebetween, which comprises clearance of the intervertebral disc space and opening the neuroforamen on one side wherein

a spinal canal is opened, inserting a first implant that has a rounded lateral side and is designed to go the furthest into the disc space laterally, introducing a second implant that has rounded leading edges on a far lateral side, with this second implant the first implant is pushed contralaterally into its first position, wherein the second implant is asymmetric to the first implant and mates with the first implant pushing it further laterally.

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15. The method of claim 14, wherein the second implant has a flat side mating with one lateral side of the first implant.

16. The method of claim 14, wherein the second implant has a flat side mating with the flat lateral side of the first implant.

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17. The method of claim 14, wherein the second cage is smaller than the first implant.

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18. The method of claim 14, wherein the first as well as the second implant each has a posterior side that is shorter than an anterior side.

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19. The method of claim 14, wherein the two implants being in the form of a cage, each implant has a hollow space which is filled with bone graft material.

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Fig.1

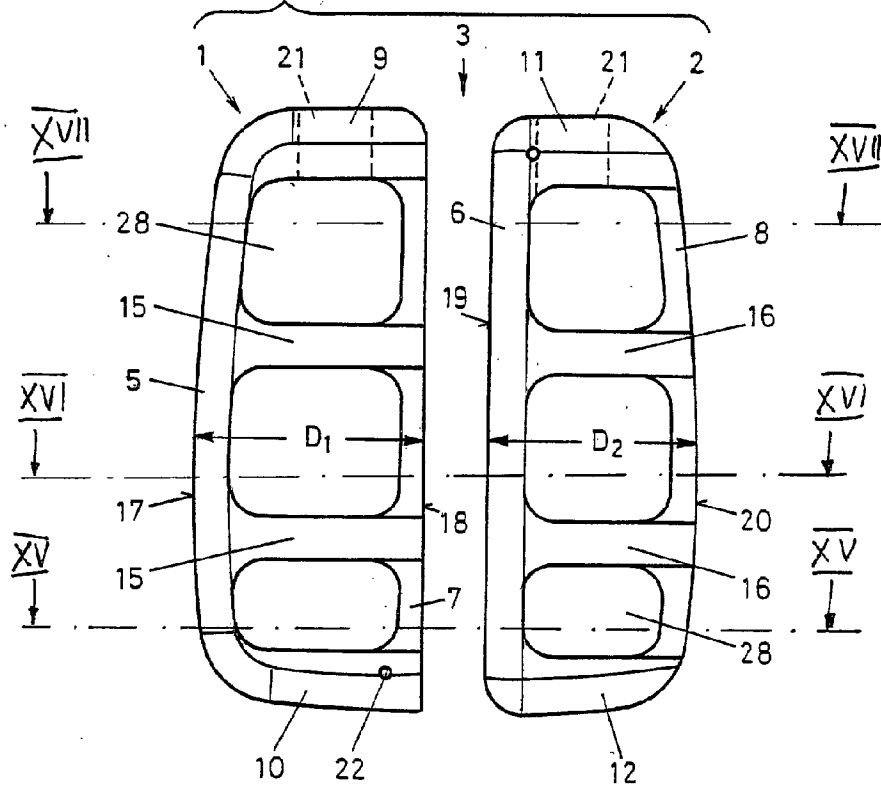


Fig. 2

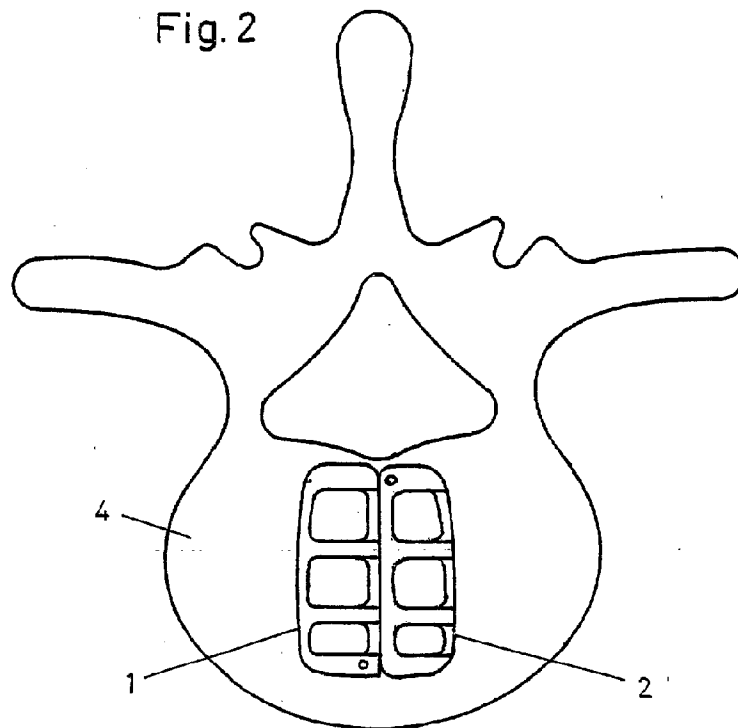


Fig. 3

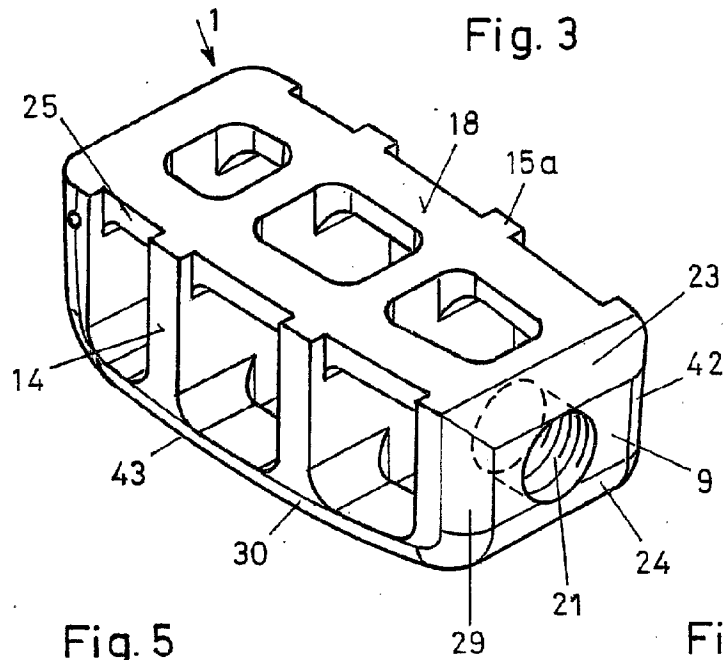


Fig. 5

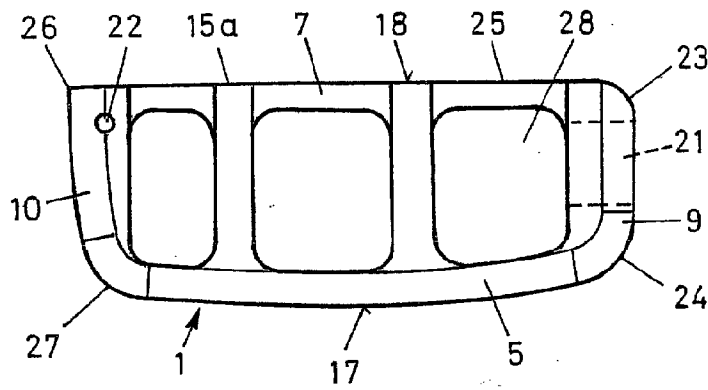


Fig. 6

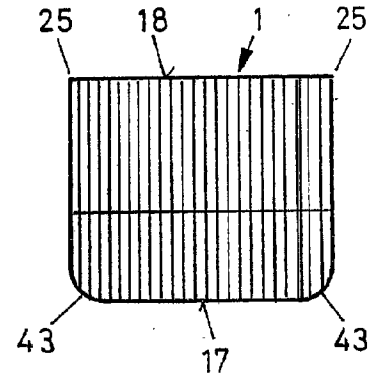
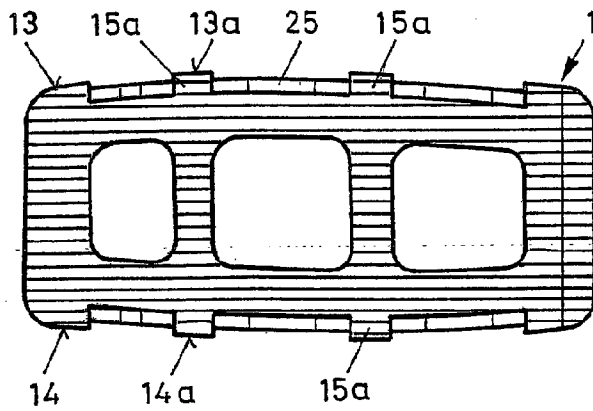
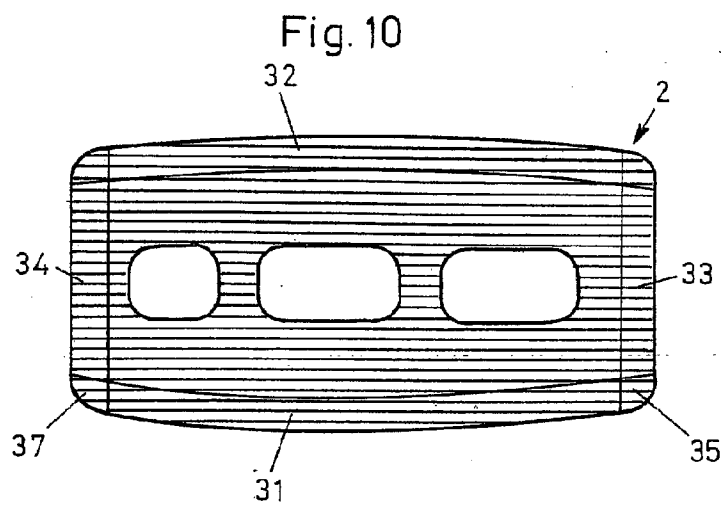
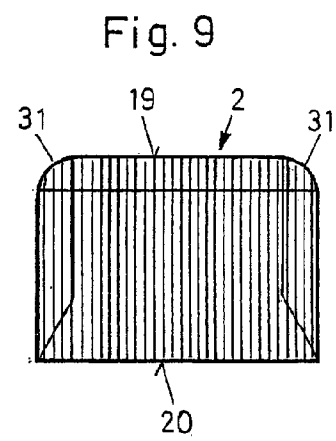
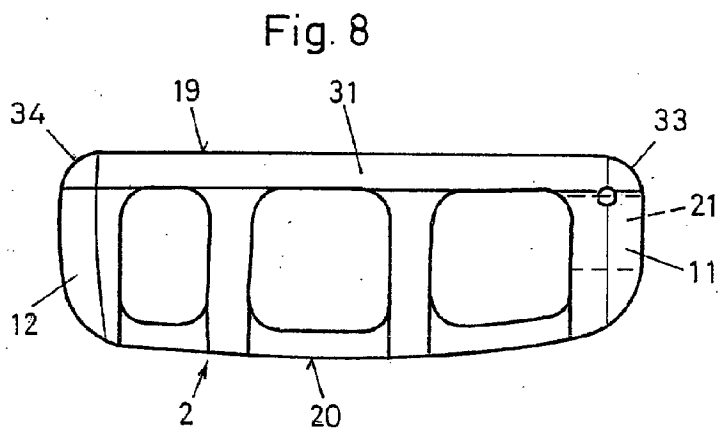
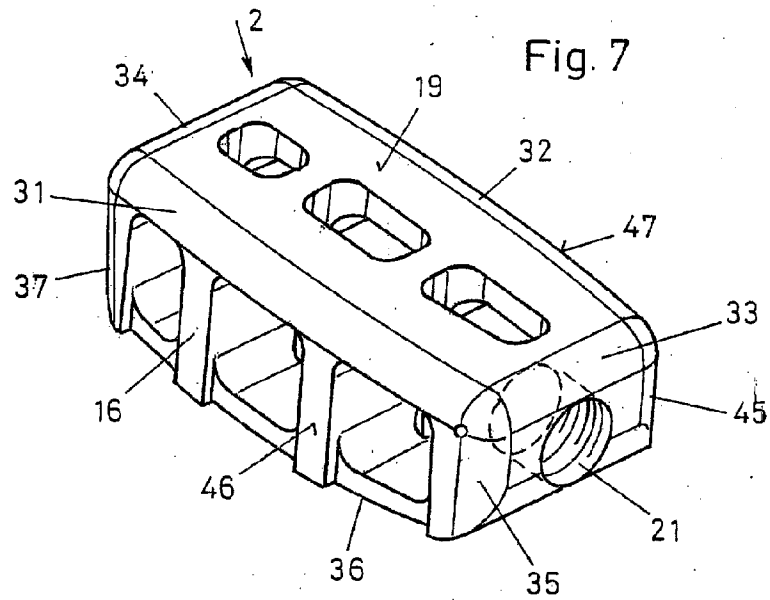
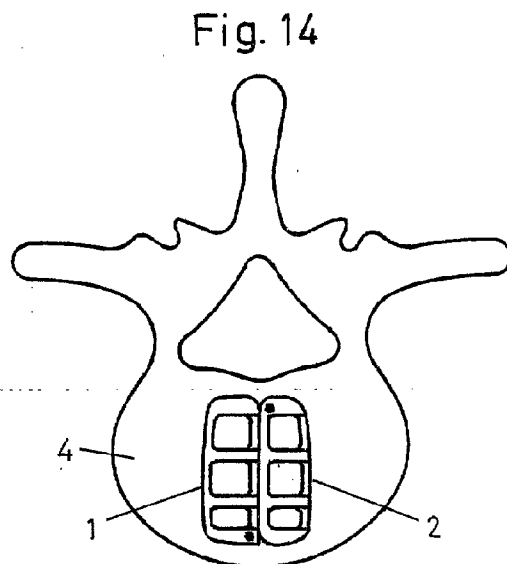
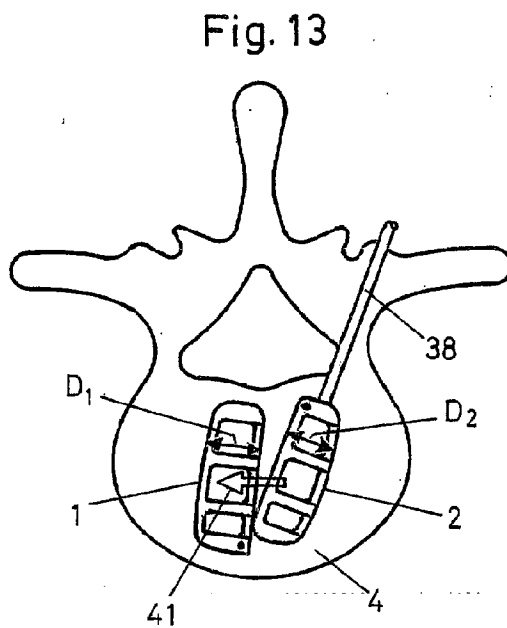
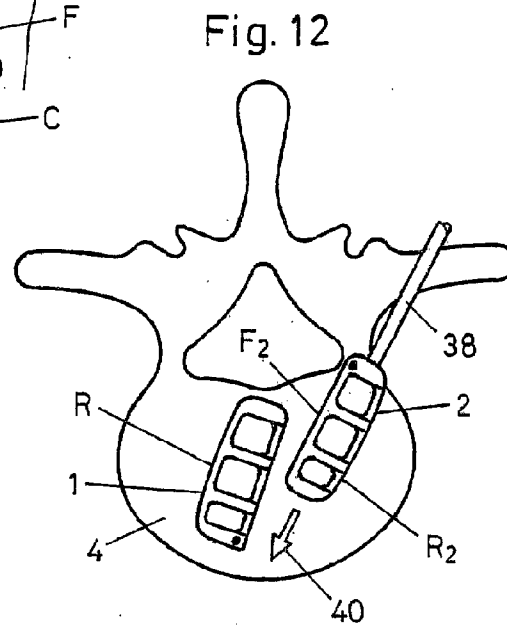
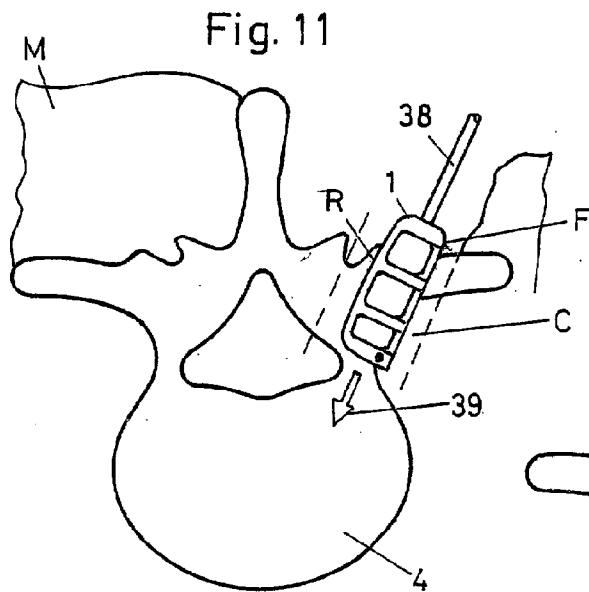
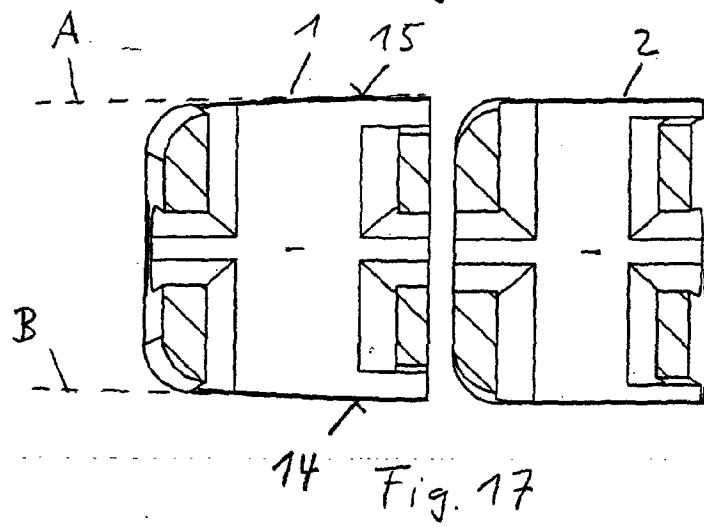
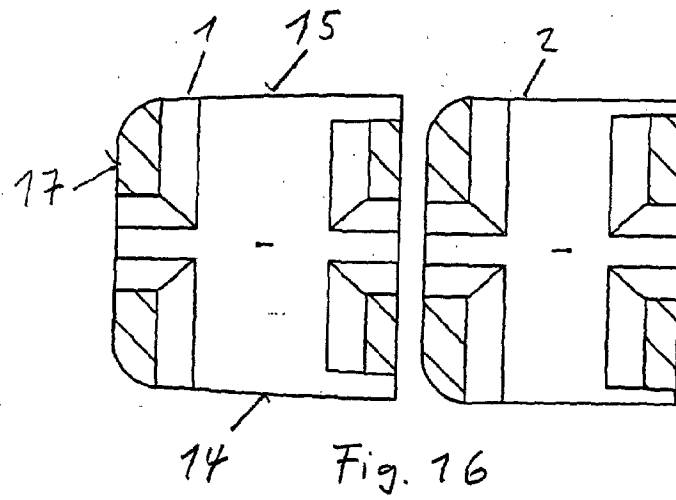
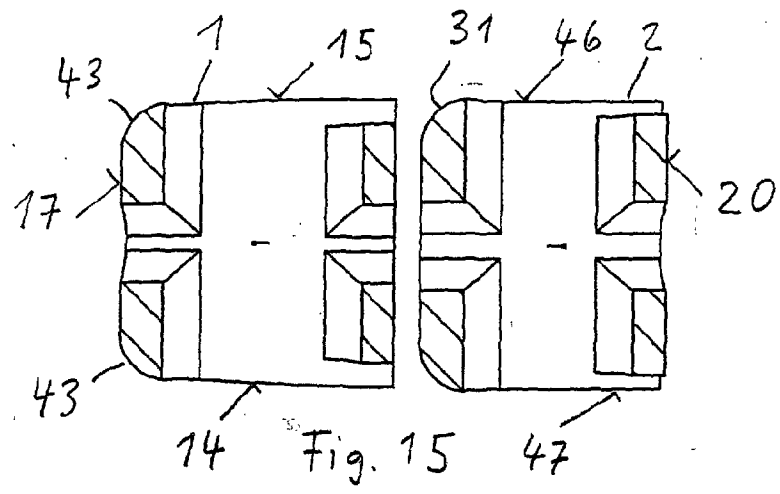


Fig. 4











European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 02 40 6120 shall be considered, for the purposes of subsequent proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	WO 00 25707 A (MICHELSON GARY K) 11 May 2000 (2000-05-11) * figures 1-5A,21,22 * * page 24, line 8 - line 19 * * page 30, line 13 - page 31, line 10 * ---	1,3,6,8, 11,12	A61F2/44 A61F2/46
A	EP 0 732 093 A (SOFAMOR DANEK GROUP INC) 18 September 1996 (1996-09-18) * claims 1-8,16,30; figures 1,25-30A,43 * ---	1-4,7,8	
A	US 6 241 770 B1 (MICHELSON GARY K) 5 June 2001 (2001-06-05) * figures 12A-12D,14A,14B * * column 9, line 29 - column 10, line 9 * ---	1,2, 4-10,13	
A	US 2002/138146 A1 (JACKSON ROGER P) 26 September 2002 (2002-09-26) * claims 7,14; figures 1-5,31-33 * -----	1,8,12	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61F
INCOMPLETE SEARCH			
<p>The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.</p> <p>Claims searched completely :</p> <p>Claims searched incompletely :</p> <p>Claims not searched :</p> <p>14-19</p> <p>Reason for the limitation of the search:</p> <p>Article 52 (4) EPC - Method for treatment of the human or animal body by surgery</p>			
Place of search		Date of completion of the search	Examiner
BERLIN		27 May 2003	Stach, R
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application I : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03.82 (P04C07)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 02 40 6120

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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27-05-2003

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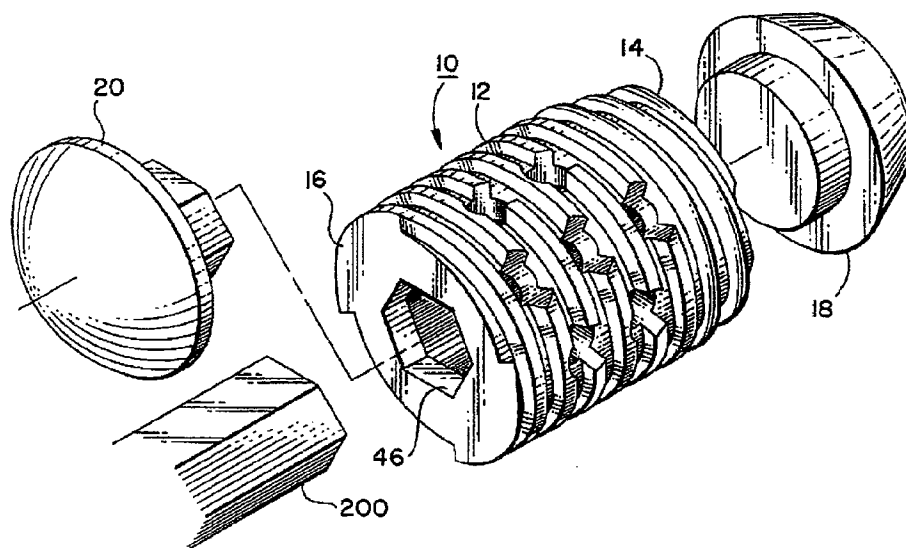
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(54) **IMPLANT RACHIDIEN**

(54) **SPINAL IMPLANT**



(57) L'invention porte sur un implant pour la stabilisation rachidienne. Dans un modèle privilégié, l'implant est décrit comme un corps cylindrique creux ayant un filetage externe et une série d'ouvertures formées radialement sur tout le corps et communiquant avec l'intérieur de ce dernier. Des bouchons, dont au moins un est fait d'un matériau perméable aux rayons X, sont prévus aux extrémités avant et arrière du corps.

(57) An implant is disclosed for use in spinal stabilization. In one preferred embodiment, the implant is described as including a hollow, cylindrical body having external threading and a plurality of openings formed radially through the body in communication with the body interior. End caps are provided on the leading and trailing ends of the body, with at least one of the end caps formed from a radiolucent material.



SPINAL IMPLANT

ABSTRACT OF THE DISCLOSURE

An implant is disclosed for use in spinal stabilization. In one preferred embodiment, the implant is
5 described as including a hollow, cylindrical body having external threading and a plurality of openings formed radially through the body in communication with the body interior. End caps are provided on the leading and trailing ends of the body, with at least one of the end
10 caps formed from a radiolucent material.

SPINAL IMPLANT

BACKGROUND OF THE INVENTION1. Field of the Invention

5 This invention pertains a surgical procedures for stabilizing the spine. More particularly, this invention pertains to a novel implant for use in such a procedure.

2. Description of the Prior Art

10 Chronic low back pain is one of the most common and perplexing problems facing the field of orthopedic surgery. In addition to patient discomfort, chronic low back pain has severe adverse societal impacts including lost income, possible chronic dependence on drugs, alcohol and public relief programs.

15 In many cases, low back pain can be avoided by preventing relative motion between spinal vertebrae (commonly referred to as intervertebral stabilization). To abate low back pain, 20 stabilization is directed to

stabilizing contiguous vertebrae in the lumbar region of the spine.

Surgical techniques are known for use in spinal stabilization. Surgical techniques seek to rigidly join
5 vertebrae which are separated by a degenerated disk. Ideally, the surgery effectively replaces the vertebra-disk-vertebra combination with a single rigid vertebra. Various surgical techniques have developed which attempt to approach or approximate this ideal.

10 One technique known in the art is to partially remove a degenerated disk and to insert a bone graft into the void formed by the removed disk. Other techniques involve the use of an implant which, acting alone or in combination with bone fragments, replace the use of bone
15 grafts. An example of such implant is shown in U.S. Pat. No. 4,501,269 to Bagby dated February 26, 1985. In Bagby, a large, cylindrical basket is driven into a hole formed between bones which are to be joined. The basket is hollow and is filled with bone fragments which are produced during
20 a boring step. Bone-to-bone fusion is achieved through and about the basket. In Bagby, the hole for the Bagby is slightly smaller than the diameter of the basket. This structure results in the spreading of the opposing bone segments upon insertion of the basket. This results in
25 taughtness, which provides initial stabilization. Eventual

fusion of the opposing bone segments results from bone growth through the basket.

Prostheses such as that shown in U.S. Pat. No. 4,501,269 are promising. However, improved implant design is necessary to enhance patient safety and the probability of a satisfactory recovery.

III.

SUMMARY OF THE INVENTION

10 According to a preferred embodiment of the present invention, an implant is disclosed for insertion into a bore formed between opposing vertebrae of an animal's spine. The implant includes a rigid body having a leading end and a trailing end spaced apart along a longitudinal axis of the body. The body has exposed threads which are 15 disposed between the leading and trailing ends. The threads are selected to engage vertebra material and draw the body along the direction of the axis upon rotation of the body about the axis. The body defines a chamber which 20 is exposed through the body by a plurality of radially extending openings. The chamber may be filled with bone fragments which can fuse with the vertebra bone material through the openings.

In an alternative embodiment of the invention disclosed herein, a generally oval-shaped implant is 25 disclosed which is hammered into an elongated bore between

two opposing vertebrae. The oval-shaped implant has enhanced surface area contact between the vertebrae and provides greater integrity against rotational motion between opposing vertebrae.

5 Other aspects of this invention are as follows:

An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said
10 spacing, said implant comprising:

a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;

said body comprising at least exposed
15 threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;

20 said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;

said body having means defining a chamber disposed within said body and said body is
25 provided with a rib disposed within said cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib dividing said chamber into a leading end chamber and a trailing end chamber, and said rib
30 including at least a rigid extension extending between and connecting diametrically opposed sides of said body;

said body having means defining at least one opening formed through said body in
35 communication with said chamber and with said

opening extending generally radially to said axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:

a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;

said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;

said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;

said body having means defining a chamber disposed within said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis, said opening comprising a hole having a

hole axis extending generally perpendicular to a plane defined by said opening at an exterior surface of said shell, said hole formed through said shell with said hole disposed with said hole axis offset from said longitudinal axis;
 5 and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and
 10 with an opposite side of said body opposing a second of said opposing vertebrae.

An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:
 20 a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;

said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;
 30

said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;

said body having means defining a chamber disposed within said body and said body is provided with a rib disposed within said
 35

cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae;

said rib is disposed between said leading and trailing ends, said implant further including a first flange at said leading end and a second flange at said trailing end, said first and second flanges extending radially into said chamber.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective exploded of view of an implant according to a preferred embodiment of the present invention;

Fig. 2 is a side elevation view of a body portion of the implant of Fig. 1;

Fig. 2A is a side elevation view of an alternative embodiment of a body portion of an implant according to the present invention;

Fig. 3 is an end view taken in elevation of the trailing end of the body portion of Fig. 2 taken along line 3-3 of Fig. 2;

5 Fig. 3A is the same view as Fig. 3 showing an alternative embodiment;

Fig. 4 is a view taken along lines 4-4 of Fig. 2;

Fig. 4a is the same view as Fig. 4 showing an alternative embodiment;

10 Fig. 5 is a view taken along line 5-5 of Fig. 2;

Fig. 6 is a view taken along lines 6-6 of Fig. 3;

Fig. 7 is an enlarged view, taken in section, of the threads of the body of Fig. 2 adjacent the trailing end;

Fig. 7A is a view, taken in section, of the threads of the body portion of Fig. 2 adjacent a leading end of the body;

Fig. 8 is a side sectional view of a leading end cap of the implant of Fig. 1;

Fig. 9 is an inside end elevation view of the end cap of Fig. 8 taken along line 9-9 of Fig. 8;

Fig. 10 is a side sectional view of a trailing end cap of the implant of Fig. 1;

Fig. 11 is an end elevation view of the end cap of Fig. 10 taken along line 11-11 of Fig. 10;

Fig. 12 is a top plan view showing insertion of a single implant of Fig. 1 into an intervertebral space;

Fig. 12A is a view taken along lines 12A-12A of Fig. 12;

Fig. 13 is a top plan view showing an alternative embodiment of the present invention in place in a vertebra;

Fig. 13A is a view taken along lines 13A-13A of Fig. 13;

Fig. 14 is a perspective view of an alternative embodiment of the present invention showing an implant body leading end, side and top;

Fig. 15 is a perspective view of the body of Fig. 14 showing a trailing end, side and top;

Fig. 16 is a top plan view of the embodiment of Figs. 14 and 15;

5 Fig. 17 is a side sectional view taken along lines 17-17 of Fig. 16;

Fig. 18 is a side elevation view of a trailing end cap for use with the embodiment of Figs. 14 and 15;

10 Fig. 19 is an end view taken in elevation of the end cap of Fig. 18;

Fig. 20 is an elevation view a trailing end of the embodiment of Figs. 14 and 15;

Fig. 21 is an elevation view of a leading end of the body of the embodiment of Figs. 14 and 15;

15 Fig. 22 is a side elevation view of the body portion of Figs. 14 and 15;

Fig. 23 is a top plan view of an assembled implant including body portion and end cap shown in place in a vertebra body;

20 Fig. 24 is an anterior elevation view showing a bore drilling sequence prior to insertion of the implant as shown in Fig. 23;

Fig. 25 is a view taken along lines 25-25 of Fig. 23;

25

V.

DESCRIPTION OF THE PREFERRED EMBODIMENT5 A. General.

Reference is now directed to Figs. 1 and 12.

Fig. 1 is an exploded perspective view of an implant according to a preferred embodiment of the present
10 invention. The implant is shown generally at 10. Fig. 12 shows the implant 10 inserted within a bore 102 formed in a human vertebra body 100.

For ease of description, the implant 10 (as well as alternative embodiments of the invention) will be
15 described for use in a human spine. Further, dimensions, when given, will be preferred dimensions for use in a specific spinal location of a particular class of humans -- notably, the L-5 vertebra of a typical adult male. It will be appreciated that the present invention is intended for
20 use in a wide variety of vertebra sizes and a wide variety of animal species. The dimensions of the implant 10 (as well as the dimensions of the alternative embodiments) will vary necessarily with the size of the vertebra in which the implant 10 is to be used. However, making variations to
25 the dimensions and sizes in order to accommodate differing sizes of vertebrae will be well within the skill of the art.

B. First Preferred Embodiment.

With reference now directed to Figs. 1-12, a first preferred embodiment of the present invention will now be described. Identical elements are numbered identically throughout.

The implant 10 includes a body 12 (shown separately in Figs. 2, 3-6) having a leading end 14 and a trailing end 16 which are spaced apart along a longitudinal axis X-X of the body 12. The implant also includes a leading end cap 18 and a trailing end cap 20 (shown separately in Figs. 8-9 and Figs. 10-11, respectively).

Body 12 is integrally constructed from a rigid, biocompatible material. While any rigid, biocompatible material (such as a ceramic) could be used, body 12 is preferably formed from titanium and/or its alloys. Titanium and/or its alloys is preferred since it is noncorrosive and fatigue resistant. Also, titanium is widely used in prosthetic devices and the material has a proven record of satisfactory performance.

With best reference to Figs. 2-7 and 7A, the body 12 includes a hollow cylindrical shell 22 of predetermined diameter D_1 (see Fig. 3). For reasons that will be later described D_1 is selected to be about .5 inches.

The shell 22 surrounds and defines an interior chamber 24. Chamber 24 has a diameter D_2 of preferably about .384 inches.

Threads 26 and 28 are formed on the exterior surface of shell 22 spirally wound around shell 22 and integral therewith. While double threading is shown, single threading or multiple threading in excess of double
5 threading could be applied. Threads 26, 28 are disposed and selected for the threads 26, 28 to engage the bone material of opposing vertebrae and draw the body 12 in the direction of axis X-X upon rotation of the body 12 about axis X-X.

10 In a preferred embodiment, body 12 is self-tapping. Mainly, the threading 26, 28 (see Fig. 2) adjacent leading end 14 is tapered as shown by angle A_1 (which is preferably about 15° , see Fig. 2). Away from the tapered end 14, and adjacent the trailing end 16, the
15 threads 26, 28 present flat, annular surfaces 30 which are in alignment and parallel to shell 22. Accordingly, the thread profile presents a generally bullet-shaped profile which is cylindrical along the majority of the body 12 and tapers inwardly toward axis X-X at the leading end 14.

20 The tapered portion of body 12 preferably has a length L_1 of about .198 inches. The overall length of body 12, L_2 , is preferably about .740 inches. (See Fig. 2).

To assist in the self-tapping, the threads 26, 28 experience a change in profile from the leading end 14 to
25 the trailing end 16. At the leading end 14, the threads are sharp, as shown in Fig. 7A. When the taper portion of

body 12 is passed, the threads 26, 28 assume a profile which is generally rectangular as shown in Fig. 7. For ease of discussion, the sharp portions of threads 26, 28 are numbered 26a, 28a in the drawings.

5 The changing thread profiles are selected to assist in advancing the implant 10 into an intervertebral space and to hold the implant 10 securely in place when fully advanced. The sharp portion of threads 26, 28 (thread portions 26a, 28a shown in Fig. 7A) cut bone better
10 and assist in advancing the implant 10. The generally rectangular thread profile (Fig. 7) has greater cross-sectional area and better opposes bone surfaces to hold the implant 10 in place.

 Preferred dimensions of the threading 26, 28 are
15 shown in Figs. 7 and 7A with a pitch, P, (distance between opposing threads) equaling about .10 inch for both the rectangular and sharp threading of Figs. 7 and 7A. The bevel B₁, of the sharp threading (Fig. 7A) is preferably about 57°. The bevel, B₂, of the rectangular thread
20 portion (Fig. 7) is preferably about 5°. The height, H, of the rectangular thread is about .10 inches. This, together with the diameter D₁ (see Fig. 3) of the shell 22 results in overall diameter of the body 12 being about .6 inches. It will be appreciated that these dimensions as well as
25 remaining dimensions given throughout this application are preferred dimensions and may be varied while retaining the

structure and function of the present invention. The scope of the claims of the present invention is not intended to be limited by dimensions which are set forth only to illustrate a preferred embodiment.

5 The body 12 has a plurality of holes 32 formed radially through the shell 22 and threads 26, 28. The holes 32 provide communication between interior chamber 24 and an exterior of the body 12.

 The holes 32 are identical and each is preferably
10 about .125 inches in diameter. Shown best in Fig. 4, each of the holes 32 includes a countersunk portion 34 at the radially outer surface of threads 26, 28. Preferably, the countersunk portion 34 has a diameter of about .155 inches.

 The countersunk portion 34 creates cutting a
15 beveled edge 33 on the rectangular threads 26, 28 in the location of the holes 32. This cutting edge 33 is best shown in Fig. 6. The cutting edges 33 chip away bone as the body 12 is rotated. The bone chips will migrate through the holes 32 into chamber 24. As will be
20 described, it is anticipated that this chipping action will enhance the bone-to-bone fusion sought with the present invention.

 In the region of the self-tapping sharp threads 26a, 28a (Fig. 7A), the threads 26a, 28a are shown self-
25 tapping in Fig. 5 to present self-tapping cutting edges 36

set at a 90° cutting angle A_3 . The cutting edges 36 are shown spaced apart by an angle A_4 of about 120° .

In the preferred embodiment as shown, holes 32 extend through the threads 26 and 28. An alternative
5 embodiment would have the threads 26 and 28 spaced apart a distance greater than that shown in the present drawings, with the holes 32 extending through the shell 22 and not passing through threads 26 and 28. Such a design presents enhanced structural integrity since the more massive
10 threads 26 and 28 are not being broken. However, such an alternative design forgoes the anticipated benefits which may be attributed to the chipping action of the cutting edges 33 of the threads adjacent holes 32.

The number of holes 32 in the body 12 as shown is
15 twenty. This number may vary. The number is selected to be as many and as large as possible (to enhance bone fusion), while not compromising the strength of the body
12.

As previously indicated, the body 12 extends from
20 a leading end 14 to a trailing end 16. Leading end 14 has a circular axial opening 40 formed therethrough in communication with chamber 24. Disposed inwardly from leading end 14 is an annular groove 42 (see Fig. 6) provided to facilitate attachment of leading end cap 18 as
25 will be described.

Trailing end 16 has an inwardly projecting flange 44. Opposing surfaces of flange 44 define a centrally located hexagon-shaped axial opening 46.

When the implant 10 is in place in an intervertebral space, circular axial opening 40 and hexagon axial opening 46 are covered by caps 18 and 20. Shown best in Figs. 8 and 9, the leading end cap 18 includes a cylindrical hub portion 50 and an annular flange 52 extending from hub portion 50. Also extending from hub portion 50 on the side opposite flange 52 is a tapered cap portion 54 which extends from a large diameter 55 and tapers inwardly to a smaller diameter terminal end 56. An angle of taper A_2 (Fig. 8) is preferably about 15° to correspond with the angle of taper A_1 (Fig. 2) of body 12. The large diameter 55 is preferably selected to equal the diameter of body 12 at leading end 14. Flange 52 is selected to be snap received into annular groove 42. So received, cap 18 is permanently attached to the leading end 14 covering axial opening 40.

Trailing end cover 20 (Figs. 10 and 11) includes an arcuate cap 58 sized to cover end 16 with a flat surface portion 59 of cap 20 abutting trailing end 16. Six flexible retaining clips 60 are provided centrally extending from surface 59. Clips 60 are sized to be snap received within hexagon-shaped opening 46. Accordingly, the cooperation of surface 59 and the barbed portion 61 of

clips 60 capture flange 44 to thereby hold trailing end cap 20 securely against trailing end 16. For reasons that will be described, each of caps 18 and 20 are preferably formed from high-density polyethylene.

5

C. Method of Use.

Referring to Figs. 12 and 12A, the method of use of the implant 10 will now be described. In use of the implant 10, a surgeon forms a bore 102 through the intervertebral space in a disk 114 separating two opposing vertebral bodies 100 and 100a. The bore 102 is sized to be as large as possible to remove disk material 114 and to at least partially cut into opposing surfaces of the bone of vertebra bodies 100, 100a. It will be appreciated that it is well within the skill of the art to form bores such as bore 102.

Fig. 12 and 12A show a bore 102 formed through a posterior approach through a spine. In a posterior approach, a surgeon approaches the vertebra through the back of the patient. Preferably, the axis of the bore 102 is formed an angle with the anterior-posterior axis, A-P, of the vertebra body 100, 100a. As shown in the preferred surgical approach, the angle A_0 between the A-P axis and the bore axis is about 10° .

It is recognized that there are limits on the maximum size of a bore 102 that can directly drilled in a vertebra body via a posterior approach. Limitations on the

diameter of the bore 102 include location of important nerves and blood vessels which can be damaged by excessively large bore drilling operations. The maximum size bore that can be cut will depend on the particular
5 location of the spine, the species of the animal, age and sex. A common safe maximum for an adult male spine in the L-5 area would be a bore diameter of about .5 inches.

For reasons that will be described, it is preferred that the bore diameter will be smaller than the
10 diameter, D_1 , of body shell 22. Specifically, it is anticipated that a bore diameter of about 3 millimeters less than diameter D_1 will be preferred. With such structure, the body 12 spreads apart opposing vertebrae upon insertion. By virtue of the spreading effect, the
15 disk annulus becomes taught, thereby providing for the initial stabilization between the opposing vertebrae. (Those skilled in the art will recognize the annulus as being the fibrous outer circumferential portion of the disk). In the drawings, the implant is shown spreading
20 apart the vertebrae and stretching the annulus. Eventual fusion of the opposing vertebrae results from bone growth through body 12, as will be described.

The implant 10 is partially assembled with leading end cap 18 snapped onto leading end 14. With trailing end
25 cap 20 removed, the implant 10 is partially placed within bore 102 with the tapered leading end 14 received within

bore 102. An advancing tool (the tip of which is shown in Fig. 1) is provided having a hexagon-shaped tip 200 complementarily sized to be received within opening 46. The tip 200 is inserted by the surgeon into opening 46.

- 5 The surgeon then turns the tool and, hence, the body 12, in a clockwise direction (from the perspective of the surgeon). The turning action of the body 12 causes the sharp threads 26a, 28a (Fig. 7A) to cut into the bone of the opposing vertebrae bodies 100, 100a to advance the body
- 10 12 into bore 102 to the fully inserted position shown in Fig. 12. The rectangular threads 26, 28 (Fig. 7) retain the body 12 in the desired axial position relative to bore 102. Leading end cap 18 covering axial opening 40 prevents disk material from migrating through axial opening 40 into
- 15 chamber 24 during insertion of implant 10 as well as during the patient's recovery phase.

With the implant body 12 fully inserted as shown in Fig. 12, the trailing end cap 18 has not yet been installed. Accordingly, axial opening 46 exposes chamber

20 24 to the surgeon once the tool tip 200 is removed. With opening 46 still exposing chamber 24, a surgeon can impact a graft medium 202 (preferably bone chips) into chamber 24 (see Fig. 12A). Any impacted bone chips will supplement bone chips that may migrate through holes 32 as a result of

25 the cutting action of cutting edges 33 against the vertebra bone surfaces.

With the graft medium fully applied to chamber 24, the surgeon snaps cap 20 into hole 46 to cover the trailing end 16. Figs. 12 and 12A show such a fully assembled and inserted implant 10. The surgeon can then close the patient through any suitable technique. With the completed implant 10 installed in the manner indicated, the bone graft 202 within chamber 24 and openings 32 fuses together with the bone of the opposing vertebrae 100, 100a to thereby join the vertebrae 100, 100a together.

As previously indicated, end caps 18, 20 are preferably formed from high density polyethylene. Such material is nonabrasive and inert, and has a slippery touch. This latter feature is particularly valuable for trailing end cap 20, which may oppose the epidural tissue.

To avoid damage or irritation of the dura, the slippery, inert, nonabrasive polyurethane trailing end cap 20 is provided. Trailing end cap 20 is intended to cover axial opening 46 and retain the bone chips within chamber 24 while providing a nonabrasive and nonirritating surface opposing the epidura. Also, like leading end cap 18, trailing end cap 20 prevents disk material from entering chamber 24.

In a preferred embodiment, the end caps 18, 20 formed of polyethylene which is radiolucent. Radiolucent material permits X-rays to pass. Accordingly, with radiolucent end caps 18, 20, an attending physician can

study the growth of bone within chamber 24 without the need for exploratory surgery.

It will be appreciated that radiolucent end cap 18, 20, while desirable in a preferred embodiment, are not necessary to the practice of the full scope of the present invention. For example, the leading end 14 could taper completely as an integral portion of the solid body 12 as shown in Fig. 2A. In such an embodiment, the body 12' assumes a more complete hollow bullet-shaped profile where the leading edge 14' includes a sharp point 15' to better assist the insertion and advancement of the body 12' into the intervertebral space.

In Figs. 12 and 12A, the implant 10 is shown installed on the left side (from the patient's perspective) of the anterior-posterior axis, A-P. For a posterior approach as shown in Fig. 12, it is anticipated that two prostheses 10 will be used, with a second implant disposed on the right side of the anterior-posterior axis, A-P, and installed in a manner identical to that of implant 10 on the left side. However, for ease of illustration, the right side implant is not shown installed. When installed, such prostheses would be positioned with the right and left prostheses being symmetrically disposed about axis A-P.

25 D. Alternative Design

Figs. 3A and 4A show an alternative. The implant 10''' of the embodiment of Figs. 3A and 4A is identical to

that discussed above except as to the placement of holes 32'''. For ease of understanding the comparison between implant 10''' and implant 10, the reader will note that Figs. 3A and 4A are the same view of implant 10''' as Figs. 3 and 4 are of implant 10.

Unlike implant 10, implant 10''' does not have holes 32''' circumferentially spaced about body 12'''. Instead, as best shown in Fig. 4A, holes 32''' are placed on diametrically opposed sides of body 12'''.

Upon insertion of the implant 10''', the surgeon positions the implant 10''' with holes 32''' opposing the bone material of the vertebra bodies 100, 100a. As a result, no disc material 114 may enter into chamber 24'''. This prevents possible interference of disc material with the bone fusion process.

To assist a surgeon, indicia markings 15''' are placed on flange 44'''. The markings 15''' are aligned with the axis of holes 32'''. The surgeon turns body 12''' into position until markings 15''' are aligned pointing to bodies 100, 100a. So positioned, the surgeon knows the holes 32''' are opposing bone and not disc material.

E. Alternative Method and Apparatus for Anterior Approach.

The foregoing description and illustration describe the insertion of an implant 10 through a posterior approach. Figs. 13 and 13A show an alternative embodiment

of the invention for use in an anterior approach where a bore 102' is formed from the front of the spine and axially aligned with the anterior-posterior axis, A-P. Since the bore 102' is formed from an anterior approach, the size
5 restrictions of a posteriorly formed bore (namely, locations of nerves and blood vessels) are largely avoided. As a result, a large diameter bore 102' can be formed. A comparison of Figs. 12A and 13A show the relative increase of bore diameter. This increase results in an enhanced
10 surface area of exposed vertebra bone and an increased amount of graft material in an implant.

The implant 10'' shown in Figs. 13 and 13A may be identical in proportional dimensions to that of implant 10, only enlarged to be received within the larger bore 102'.
15 However, the implant 10'' shown in Figs. 13 and 13A differs from that shown in Figs. 12 and 12A. Namely, the implant 10'' shown in Figs. 13 and 13A does not include a tapered leading end. Instead, the entire implant body 12'' is cylindrical-shaped to illustrate that, while a tapered
20 leading end is preferred, it is not necessary to practice the teachings of the present invention.

25 F. Further Alternative Embodiments.

Figs. 15-25 illustrate yet a further embodiment of an implant for use in spinal stabilization. As shown in those figures, the implant 120 (shown assembled in Figs. 23 and 25) includes a body portion 122 (shown in perspective

in Figs. 14 and 15) which is generally oval-shaped in cross section and formed from rigid, biocompatible material (preferably titanium). The body 122 includes generally flat side walls 124, 126 joined by upper and lower semi-cylindrical arcuate ribs 128. Arcuate ribs 128 are spaced apart to define a plurality of upper and lower semi-circular arcuate openings 130 which provide communication between a hollow interior 132 of body 122 and an exterior. The ribs 128 define upper and lower walls of the implant 10 120 with the walls having openings 130 therethrough.

Body 122 extends from a leading or anterior end 133, and a trailing or posterior end 134. Anterior end 133 has a centrally positioned cover plate 136 which partially covers end 132 but leaves upper and lower semi-circular axial openings 138 exposing interior 132 through end 133. Shown best in Fig. 16, body 122 is tapered at the leading end 133, with the side walls 124, 126 tapering inwardly at an angle A_7 of preferably 10° each. Also, the upper and lower planar of the ribs 128 are tapered inwardly as best shown in Fig. 22 at a preferred taper angles, A_8 , of about 3° . The edges defined by the juncture of walls 124, 126, ribs 128 and end 133 are rounded to facilitate insertion of implant 120 as will be described.

The posterior end 134 (shown in Fig. 14) has an axial opening 142 which communicates with the body interior 132. A pair of opposing retaining ribs 146 are shown

partially extending from the side walls 124, 126 into opening 142. A posterior end cap 147 is provided with an arcuate, smooth cap 149 sized to cover end 134 and opening 142. End cap 147 has retaining clips 148 selected to snap
 5 behind ribs 146 to thereby attach cap 147 against end 144.

10 G. Method of Use of Alternative Embodiment.

implant 120 is intended for use in a posterior approach with two prostheses 120 being inserted on opposite sides of the anterior-posterior axis of a vertebra. For ease of illustration, only one prosthetic device is shown
 15 inserted in Figs. 23-25. Fig. 24 shows a method for drilling the bore 154 to receive the oval-shaped implant 120. As shown in Fig. 24, three circular bores 150, 151, 152 are drilled in vertical alignment in opposing vertebra bodies 100', 100a' and separating disk 114'. The three bores 150, 151, 152 cooperate to form a generally oval-shaped bore 154.

Bore 154 is sized to be slightly smaller than the dimensions of body 122. The surgeon inserts the tapered
 25 leading end 133 into bore 154. With any suitable hammering mechanism, the surgeon then impacts on the uncapped posterior end 134 to drive the implant 120 into the bore 154 as shown in Figs. 23 and 25. The tapers A₁ and A₂

(Figs. 16 and 22) and the rounded corners on leading end 133 assist in the insertion.

With the implant fully inserted, the surgeon fills the chamber 132 with graft medium 155 (again, preferably bone chips), the surgeon then installs the polyethylene posterior cap 147 to cover posterior end 134 and provide a non-abrasive surface opposing the epidura.

The implant 120 of Figs. 14-25 greatly enhances the depth of insertion into opposing vertebrae 100', 100a' through a posterior approach. Namely, an oval bore 154 can be formed having a height, H_2 (see Fig. 24) equal to about three times the diameter of bores 102 described in previous embodiments. This added depth directly into the bone material of the vertebra body 100', 100a' increases the surface area available for grafting to thereby enhance the probability of a successful graft. Also, the increased depth into each of the vertebra bodies provides increased surface to prevent relative rotation of the opposing vertebrae 100', 100a' about the axis of the spine.

The side walls 124, 126 of the implant do not have openings and, therefore prevent disk material from penetrating into the chamber and thereby interfering with the bone fusion. The implant 120 is sized for the upper and lower openings 133 to be located completely above and below, respectively, the disk layer 114'. Also, plate 136 on end 133 is sized to be about the thickness of layer 114'

(or slightly greater) to prevent disk material from entering the interior 132 of implant 120. Openings 138 are positioned to oppose only bone of vertebra 100', 100a'.

From the foregoing detailed description of the
5 present invention, it has been shown how the invention has been attained in a preferred embodiment, including alternative embodiments. However, modifications and equivalents of these concepts are intended to be included within the scope of this invention.

10

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:
 - a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;
 - said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;
 - said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;
 - said body having means defining a chamber disposed within said body and said body is provided with a rib disposed within said cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib dividing said chamber into a leading end chamber and a trailing end chamber, and said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;
 - said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis; and
 - said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

2. An implant according to Claim 1 wherein said implant includes means spaced away from said trailing end for receiving an advancing tool for advancing said implant into said bore.
3. An implant according to Claim 1 wherein said rib has a rib opening formed therein, said rib opening sized to receive a distal end of an insertion tool for insertion of said distal end into said rib opening and for turning said implant upon turning of said tool.
4. An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:
- a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;
 - said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;
 - said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;
 - said body having means defining a chamber disposed within said body;
 - said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis, said opening comprising a hole having a hole axis extending generally perpendicular to a plane defined by said opening at an exterior surface of said shell, said hole formed through said shell with said hole disposed with said hole axis offset from said longitudinal axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae.

5. An implant according to Claim 4 wherein
 said body has a plurality of walls defining a plurality of holes each having a hole axis extending generally parallel to said walls and perpendicular to a plane defined by said holes at an exterior surface of said body, said holes formed through said body in communication with said chamber, said holes disposed with said hole axes not intersecting said longitudinal axis;
 said holes have cutting edges positioned to oppose said vertebrae to chip bone from said vertebrae into said holes.

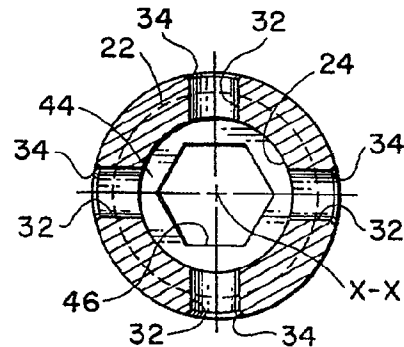
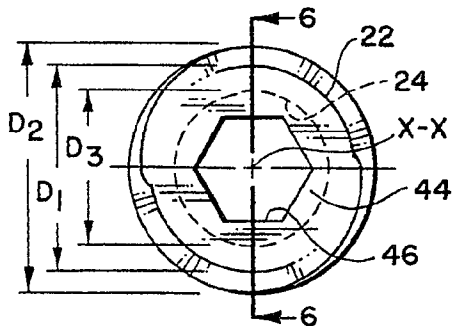
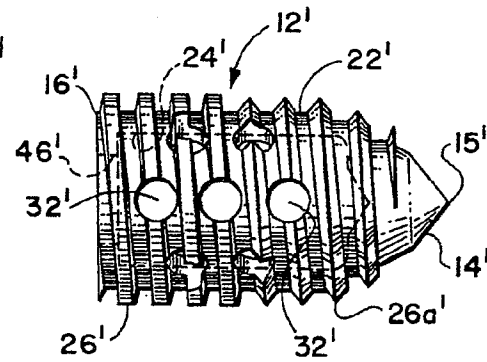
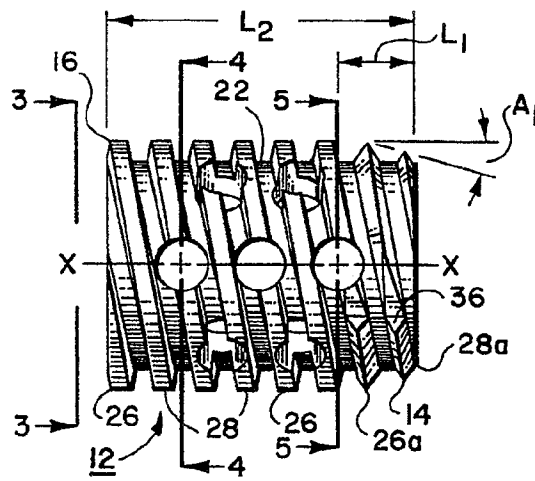
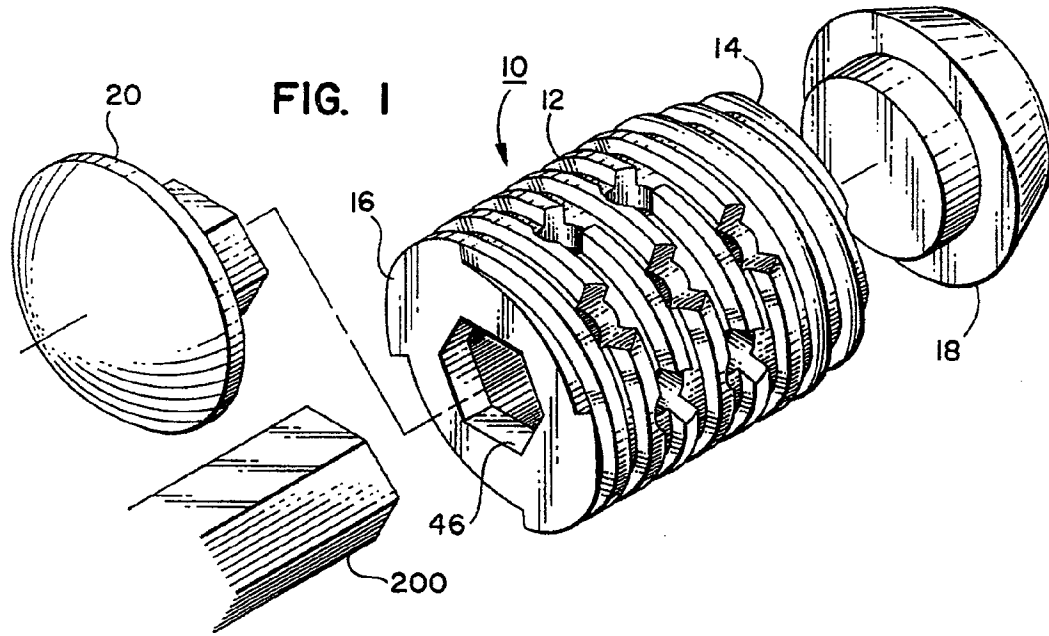
6. An implant for insertion into a bore formed between opposing vertebrae of a spine where said vertebrae are separated by a spacing with a disk material having an annulus disposed within said spacing, said implant comprising:
 a rigid body having a leading end and a trailing end spaced apart by a longitudinal axis of said body;
 said body comprising at least exposed threads disposed at least partially between said leading end and said trailing end, said threads selected to engage vertebra material and draw said body along a direction of said axis upon rotation of said body about said axis;
 said body having a hollow, generally cylindrical shell with said threads disposed on an exterior surface of said shell;
 said body having means defining a chamber disposed within said body and said body is provided with a rib

disposed within said cylindrical shell and extending radially inwardly toward said longitudinal axis, said rib including at least a rigid extension extending between and connecting diametrically opposed sides of said body;

said body having means defining at least one opening formed through said body in communication with said chamber and with said opening extending generally radially to said axis; and

said body having a transverse dimension generally transverse to said longitudinal axis and dimensioned so as to be greater than said bore for said body to urge said opposing vertebrae apart and to stretch said annulus upon insertion of said body into said bore between said vertebrae with a portion of said body opposing a first of said opposing vertebrae and with an opposite side of said body opposing a second of said opposing vertebrae;

said rib is disposed between said leading and trailing ends, said implant further including a first flange at said leading end and a second flange at said trailing end, said first and second flanges extending radially into said chamber.



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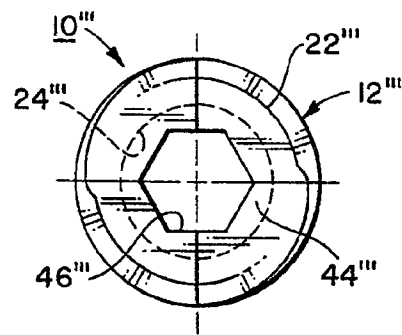


FIG. 3A

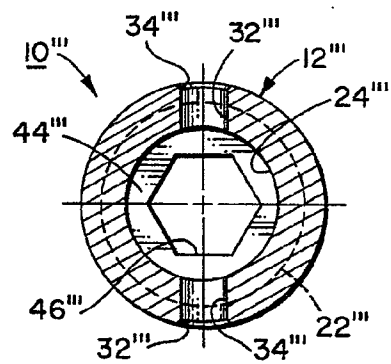


FIG. 4A

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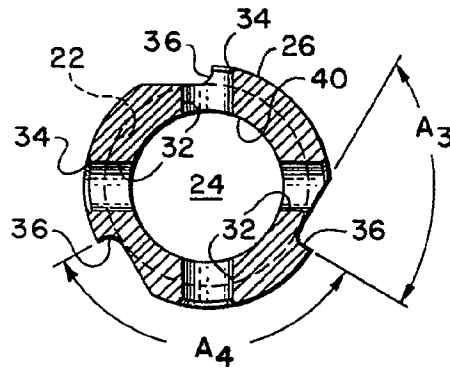


FIG. 5

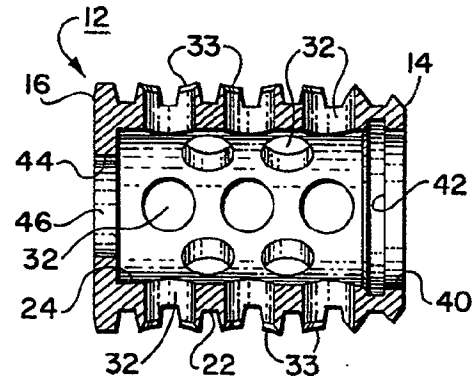


FIG. 6

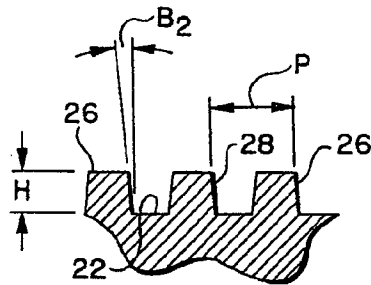


FIG. 7

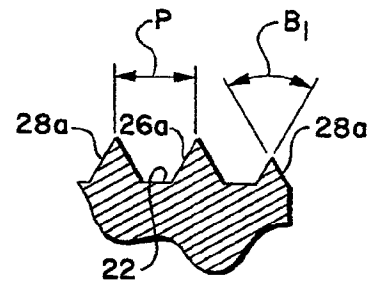


FIG. 7A

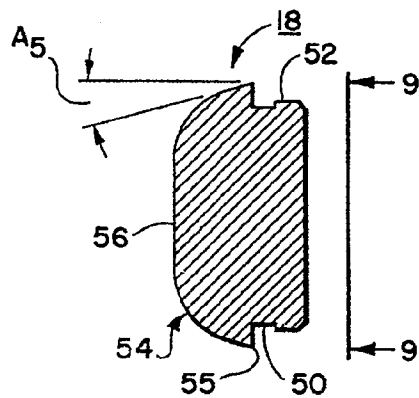


FIG. 8

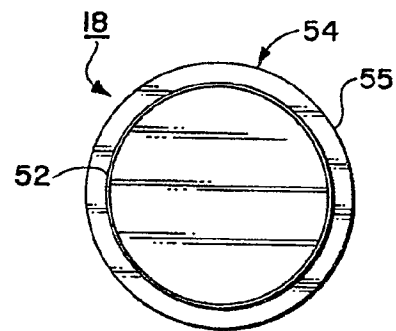


FIG. 9

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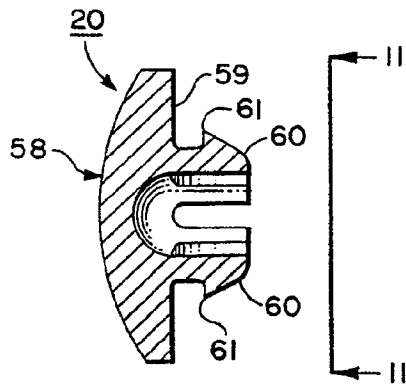


FIG. 10

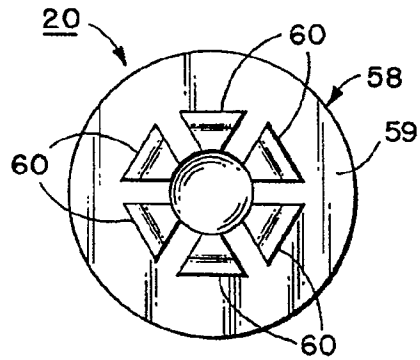


FIG. 11

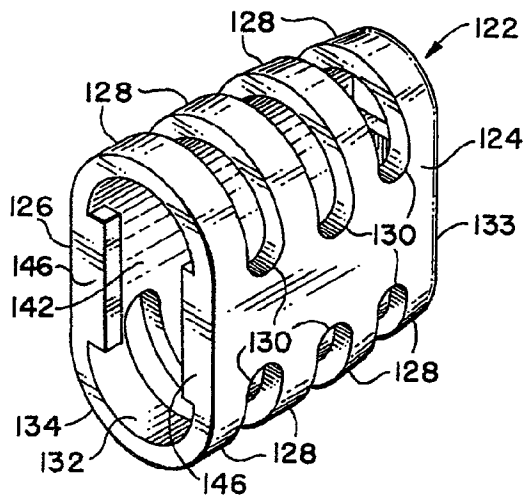


FIG. 14

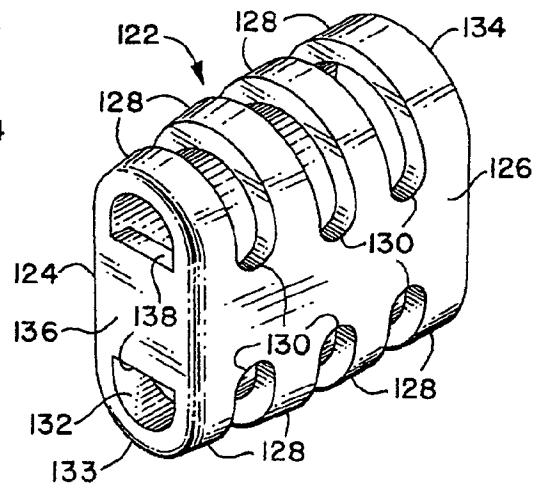


FIG. 15

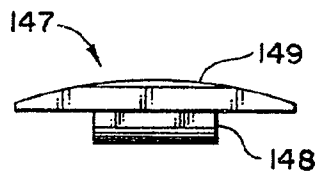


FIG. 18

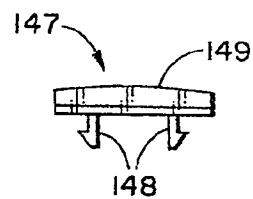


FIG. 19

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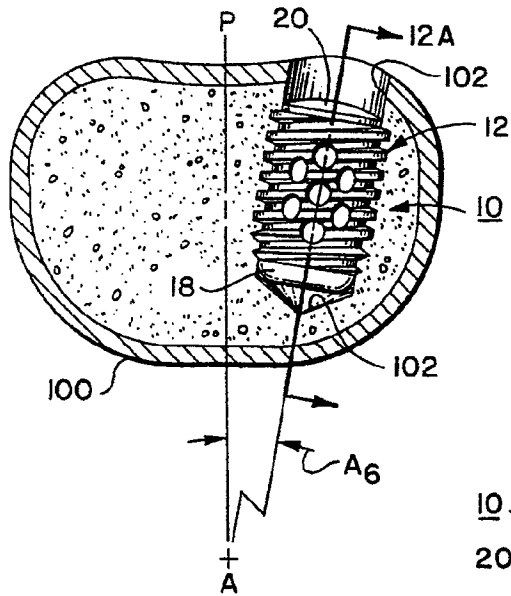


FIG. 12

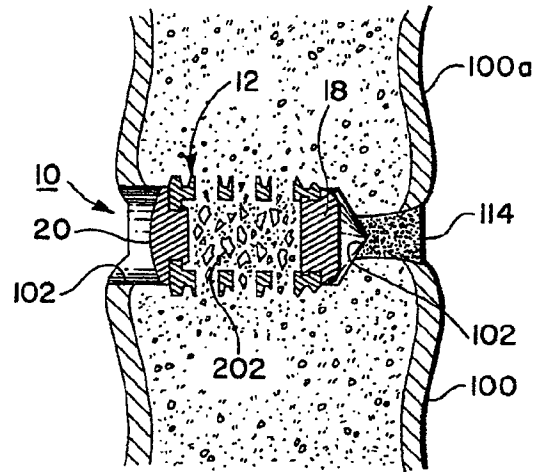


FIG. 12A

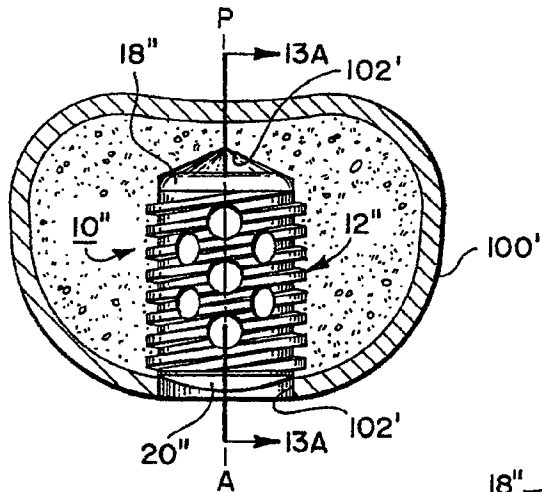


FIG. 13

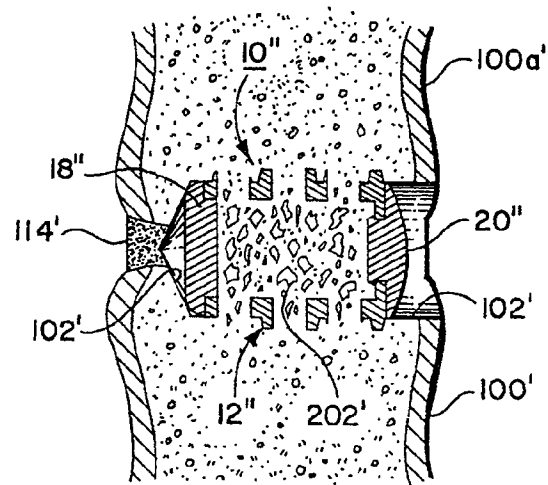


FIG. 13A

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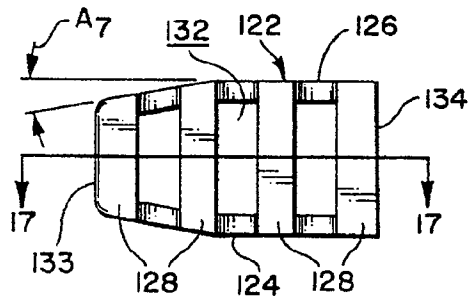


FIG. 16

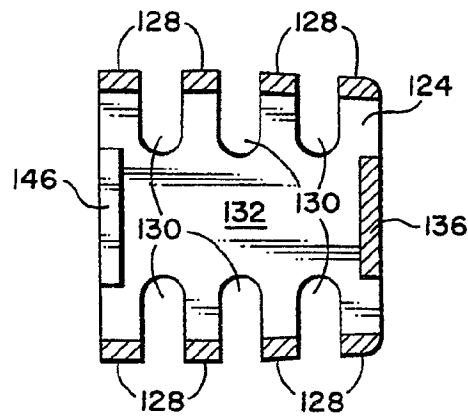


FIG. 17

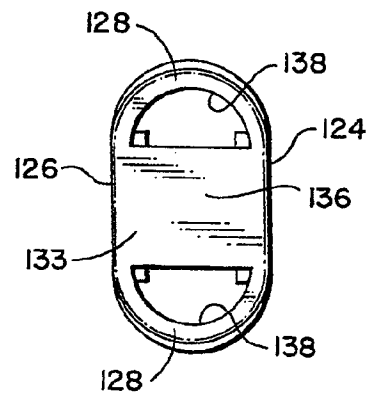


FIG. 21

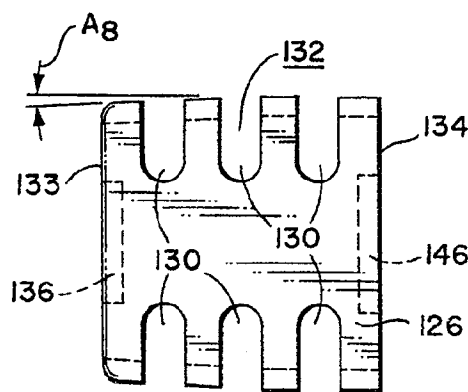


FIG. 22

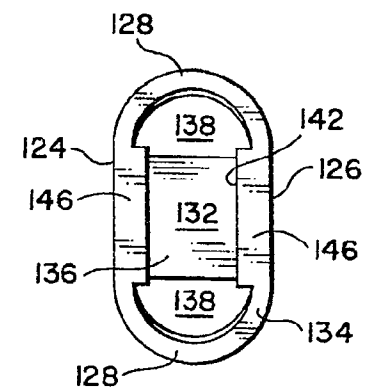


FIG. 20

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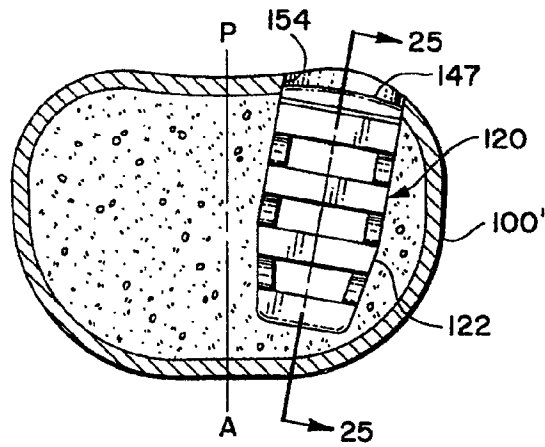


FIG. 23

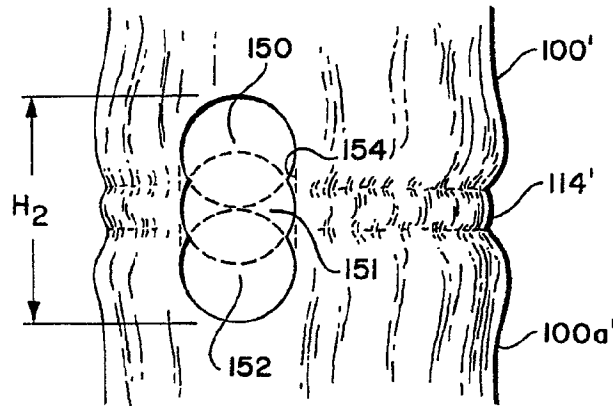


FIG. 24

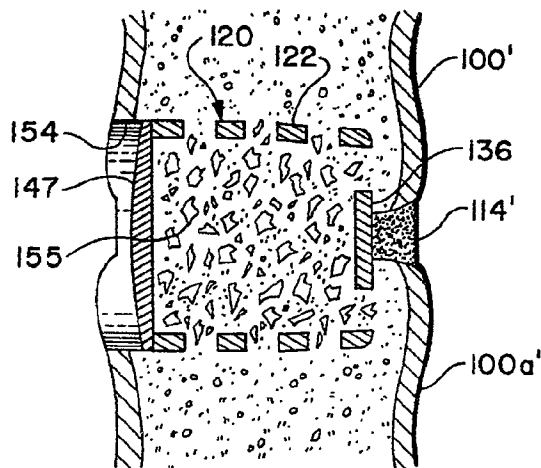


FIG. 25

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ARTIFICIAL VERTEBRA**Publication number:** CA2088066**Publication date:** 1992-01-25**Inventor:** RASHEED MOHAMED I (AT)**Applicant:** RASHEED MOHAMED I (AT)**Classification:**

- international: **A61B17/58; A61F2/30; A61F2/44; A61B17/70;**
A61B17/80; A61F2/00; A61B17/58; A61F2/30;
A61F2/44; A61B17/68; A61B17/70; A61F2/00; (IPC1-7):
A61F2/44

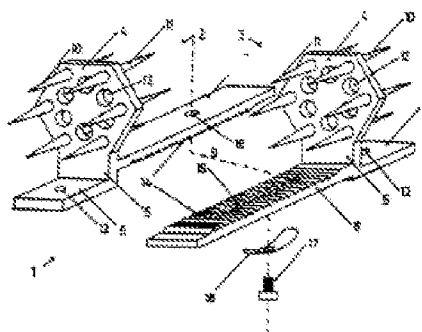
- European: A61F2/30G; A61F2/44

Application number: CA19912088066 19910724**Priority number(s):** AT19900001557 19900724**Also published as:**

WO9201428 (A1)
EP0540559 (A1)
EP0540559 (A0)

[Report a data error here](#)**Abstract of CA2088066**

The subject matter of this invention is a spinal prosthesis for the replacement of one or more destroyed vertebrae, with two supporting plates which lie close to the end surfaces of adjacent healthy vertebrae. The supporting plates have spikes for providing an anchorage in these adjacent vertebrae and are connected by a spacer, the length of which can be adjusted. This spacer (9) is arranged off-center relative to the longitudinal axis of the spinal prosthesis (1), which is defined by the centers of the supporting plates (4), and has two rails (7,8) with meshing teeth (14) along the surfaces that face each other. The rails (7,8) are connected to each other by means of a screw (17). Between the supporting plates (4), a recipient site for the implant (32) consisting of a natural and/or artificial material is left open. The subject matter of this invention also includes a device for handling this spinal prosthesis, in particular for inserting the spinal prosthesis into the spinal column.



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Int. Cl. 2:

A 61 F 1/00

① **BUNDESREPUBLIK DEUTSCHLAND**

DEUTSCHES



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17. 5. 79

⑮

Unionspriorität:

⑯ ⑰ ⑱

⑤

Bezeichnung:

Schultergelenk-Totalendoprothese

⑦

Anmelder:

Mecron Medizinische Produkte GmbH, 1000 Berlin

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DE 27 50 648 A 1

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1191/17.080 DE

10. November 1977

A n m e l d u n g
der Firma
MECRON Medizinische Produkte
GmbH.
Dederlingstrasse 3-7
1000 Berlin 42

Ansprüche :

1. Schultergelenk-Totalendoprothese, bestehend aus einer am Schulterblatt befestigten Pfanne, einem am Oberarmknochen befestigten, in der Pfanne ruhenden Kugelkopf und einem den Kugelkopf umfassenden, an der Pfanne befestigten Haltering, dadurch g e k e n n z e i c h n e t , daß der Haltering (4) über einen Verschluß nach Art eines Bajonettverschlusses (8,9) mit der Pfanne (1) verbunden ist.

2. Schultergelenk-Totalendoprothese nach Anspruch 1, dadurch g e k e n n z e i c h n e t , daß der Haltering (4) - vorzugsweise vier - nach außen ragende Segmentnasen (8) und die Pfanne (1) nach innen ragende Segmentnasen (9) besitzt.

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3. Schultergelenk-Totalendoprothese nach Anspruch 2, dadurch gekennzeichnet, daß die Segmentnasen (9) der Pfanne (1), vorzugsweise nach außen abgeschrägt, an einem den Haltering (4) im zusammengefügt Zustand umgebenden Rand (12) sitzen.
4. Schultergelenk-Totalendoprothese nach Anspruch 2 oder 3, dadurch gekennzeichnet, daß die Anlageflächen der Segmentnasen (8,9) in einer Ebene liegen.
5. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 2 - 4, dadurch gekennzeichnet, daß die Segmentnasen (9) der Pfanne (1) im zusammengesetzten Zustand an der äußeren Mantelfläche des Halteringes (4) mit Spiel anliegen.
6. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 2 - 5, dadurch gekennzeichnet, daß die den Anlageflächen gegenüberliegenden Flächen der Segmentnasen (8) des Halteringes (4) in der Ebene der der Pfanne (1) zugewandten Stirnfläche des Halteringes (4) liegen.
7. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 2 - 6, dadurch gekennzeichnet, daß die Abstände in peripherischer Richtung zwischen den Segmentnasen (8,9) gleich der Länge der Segmentnasen (8,9) in peripherischer Richtung plus Spiel sind, wobei vorzugsweise die beim Einsetzen des Halteringes (4) zuerst aneinander vorbeilaufenden Kanten (20) der Nasen (8,9) abgeschrägt sind.
8. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 1 - 7, dadurch gekennzeichnet,

daß Elemente (5,11) vorgesehen sind, welche den Haltering (4) in der verriegelten Lage vorzugsweise lösbar halten.

9. Schultergelenk-Totalendoprothese nach Anspruch 8, dadurch gekennzeichnet, daß sich zwischen Haltering (4) und Pfanne (1) ein Flachring (5) mit mindestens einem radial abragenden Steg (11), vorzugsweise zwei diametral einander gegenüberliegenden Stegen, befindet und daß sich in dem Haltering (4) und in der Pfanne (1) Ausnehmungen (13,14) befinden, in die der (die) Steg(e) (11) zwecks Verriegelung des Halteringes (4) gegenüber der Pfanne (1) greifen.

10. Schultergelenk-Totalendoprothese nach Anspruch 9, dadurch gekennzeichnet, daß die Ausnehmungen Nuten (13,14) sind.

11. Schultergelenk-Totalendoprothese nach Anspruch 9 oder 10, dadurch gekennzeichnet, daß sich die Ausnehmungen (13,14) in der Mitte zwischen den Segmentnasen (8,9) befinden.

12. Schultergelenk-Totalendoprothese nach Anspruch 10 und 11, dadurch gekennzeichnet, daß in dem Rand (12) der Pfanne (1) mindestens eine senkrecht zu seiner Stirnfläche einspringende Nut (13) vorgesehen ist.

13. Schultergelenk-Totalendoprothese nach Anspruch 10 und 11, dadurch gekennzeichnet, daß in der Mantelfläche des Ringes (4) mindestens eine Nut (14) vorgesehen ist.

14. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 9 - 13, dadurch gekennzeichnet, daß der (die) Steg(e) (11) federnd ausgebildet ist (sind).

15. Schultergelenk-Totalendoprothese nach Anspruch 14, dadurch gekennzeichnet, daß der (die) Steg(e) (11) bleibend nachverformbar ist (sind).

16. Schultergelenk-Totalendoprothese nach Anspruch 9, dadurch gekennzeichnet, daß der (die) Steg(e) (11) gekröpft ist (sind).

17. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 9 - 16, dadurch gekennzeichnet, daß der Haltering (4) gegen einen Federwiderstand, ausgeübt durch die Stege (11), auf den Grund der Pfanne (1) drückbar ist.

18. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 9 - 16, dadurch gekennzeichnet, daß der Flachring (5) an dem Haltering (4) befestigt ist.

19. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 1 - 18, dadurch gekennzeichnet, daß der Mittelpunkt (16) des Kugelkopfes (2) im zusammengefügt Zustand innerhalb der den Kugelkopf (2) aufnehmenden Ausnehmung des Halteringes (4,7) liegt.

20. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 1 - 19, dadurch gekennzeichnet, daß der der Pfanne (1) abgewandte Randbereich (15) des Ringes (4) den Verkippungswinkel des von dem Kugelkopf (2) abragenden Schaftes (3) begrenzt und daß dieser Verkippungswinkel größer als 75° ist.

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21. Schultergelenk-Totalendoprothese nach Anspruch 20, dadurch g e k e n n z e i c h n e t , daß dieser Randbereich (15) so weit vom Zentrum (16) der Prothese entfernt ist, daß bei Anlage des Schaftes (3) an diesem Randbereich (15) ein vertretbares Hebelverhältnis gegeben ist.

22. Schultergelenk-Totalendoprothese nach Anspruch 20 oder 21, dadurch g e k e n n z e i c h n e t , daß der im übrigen abgeflachte Schaft (3) in dem Bereich, der sich an den Randbereich (15) anlegt, rund ist.

23. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 1 - 22, dadurch g e k e n n z e i c h n e t , daß der Schaft (3) im Abstand von dem Kugelkopf (2) abgewinkelt ist, wobei der Winkel parallel zu den Abflachungen des Schaftes (3) liegt.

24. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 1 - 23, dadurch g e k e n n z e i c h n e t , daß der Schaft (3) im Bereich seines einzuzementierenden Teils leicht konisch und glatt ist.

25. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 1 - 24, dadurch g e k e n n z e i c h n e t , daß bei ansteigenden Biegekräften der Schaft (3) seine Form verändert, bevor das Gelenk zerstört wird.

26. Schultergelenk-Totalendoprothese nach einem oder mehreren der Ansprüche 1 - 25, dadurch g e k e n n z e i c h n e t , daß die Pfanne (1) außen Marken (19) aufweist, auf die beim Zusammenstecken die Stege (11) ausgerichtet werden.

MECRON Medizinische Produkte GmbH.

1191/17.080 DE

"Schultergelenk-Totalendoprothese"

Die Erfindung bezieht sich auf eine Schultergelenk-Totalendoprothese, bestehend aus einer am Schulterblatt befestigten Pfanne, einem am Oberarmknochen befestigten, in der Pfanne ruhenden Kugelkopf und einem den Kugelkopf umfassenden, an der Pfanne befestigten Haltering.

Der Erfindung liegt die Aufgabe zugrunde, eine einfach montierbare, haltbare Prothese dieser Art zu schaffen.

Diese Aufgabe wird erfindungsgemäß dadurch gelöst, daß der Haltering über einen Verschuß nach Art eines Bajonettverschlusses mit der Pfanne verbunden ist.

Eine solche Prothese kann notfalls auch wieder demontiert werden.

Weitere Einzelheiten der Erfindung ergeben sich aus der Zeichnung. Darin zeigen:

Fig. 1 einen Schnitt durch eine Schultergelenk-Totalendoprothese;

Fig. 2 in verkleinertem Maßstab eine Einzelheit derselben, nämlich den Ring im Schnitt;

Fig. 3 eine Draufsicht auf den Ring;

Fig. 4 in verkleinertem Maßstab eine Einzelheit der in Fig. 1 dargestellten Endoprothese, nämlich die Pfanne im Schnitt;

Fig. 5 eine Draufsicht auf die Pfanne;

Fig. 6 in verkleinertem Maßstab eine Ansicht des Schaftes
und

Fig. 7 eine Draufsicht dazu.

Die Prothese besteht aus einer am Schulterblatt befestigten Pfanne 1, einem Kugelkopf 2, der über einen Schaft 3 am Oberarm befestigt ist, einem Haltering 4 und einem Federring 5. Pfanne 1 und Haltering 4 besitzen Gleitschalen 6 und 7 aus Polyäthylen und werden über Segmentnasen 8 und 9 zusammengehalten.

Beim Zusammenbau wird der Haltering 4 in die Pfanne 1 geschoben, wobei seine Segmentnasen 8 zunächst zwischen den Segmentnasen 9 vorbeigeführt werden, bis der Haltering 4 auf dem Grund 10 der Pfanne 1 aufsitzt. Dann wird der Haltering 4 gedreht, bis die Segmentnasen 8 hinter den Segmentnasen 9 liegen. Der Federring 5 besitzt zwei oder vier Stege 11, die gekröpft sind und beim Zusammen-drehen über den Rand 12 der Pfanne 1 gleiten, bis sie in Nuten 13 einrasten und dadurch den Haltering 4, in dessen Nuten 14 die Mittelteile 15 der Stege 11 ruhen, gegenüber der Pfanne 1 arretieren.

Bei einer eventuell notwendig werdenden Demontage werden die Stege 11 entsprechend angehoben.

Der im übrigen abgeflachte Schaft 3 ist in dem Bereich, in dem er dem Haltering 4 anliegt, rund. Der größte Verkipfungswinkel des Schaftes ist somit nach allen Richtungen hin der gleiche.

Der Mittelpunkt 16 des Kugelkopfes sitzt außerhalb der Pfanne 1. Auf diese Weise wird erreicht, daß die Segment-

nasen 9 höher und damit stabiler sein können als dann, wenn der Mittelpunkt 16 tiefer (in bezug auf Fig. 1) läge.

Die Nasen 9 sind nach außen abgeschrägt, dies deshalb, damit die Stege 11 einen vertretbaren Hebelarm zwischen dem Knickpunkt 17 und dem Auflagepunkt 18 besitzen.

Die Nuten 13 und 14 liegen in der Mitte zwischen den Segmentnasen. Dadurch wird erreicht, daß der Haltering 4 rechts wie links herum in seine Sollstellung gedreht werden kann.

Der Verkipfungswinkel des Schaftes 3 beträgt mindestens 75° nach allen Seiten. Die Forderung, einen möglichst großen Verkipfungswinkel vorzusehen, erfüllt das erfindungsgemäße Gelenk somit.

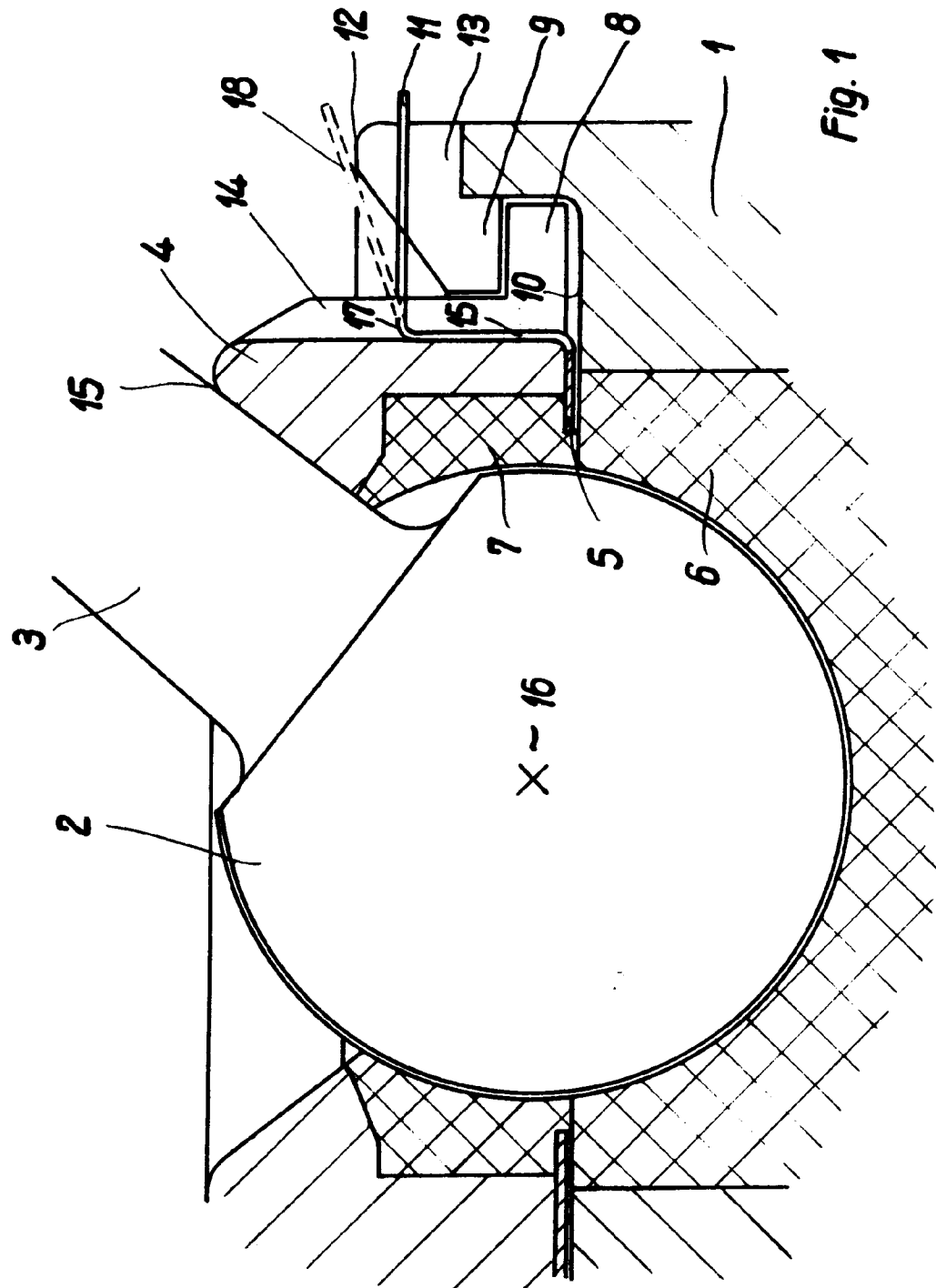
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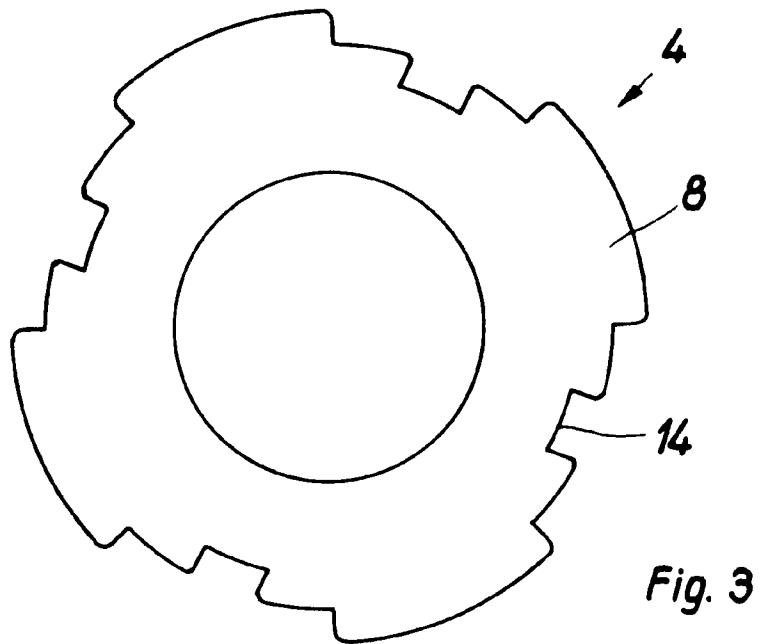
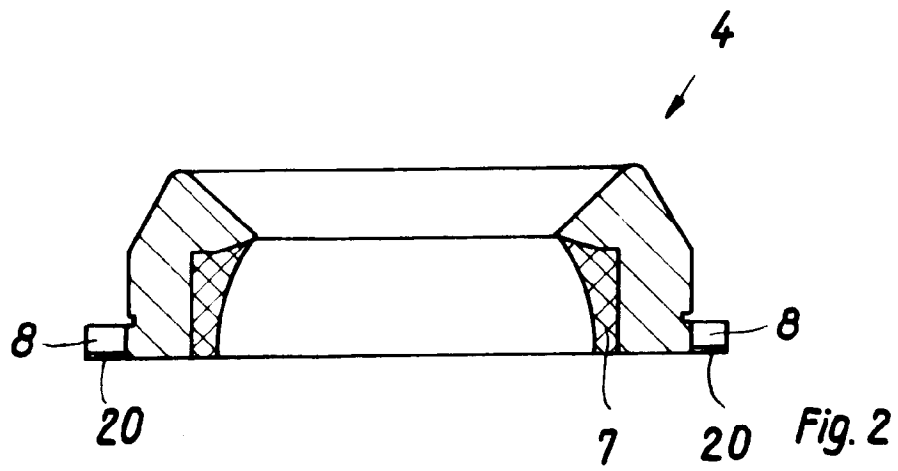
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Fig. 1



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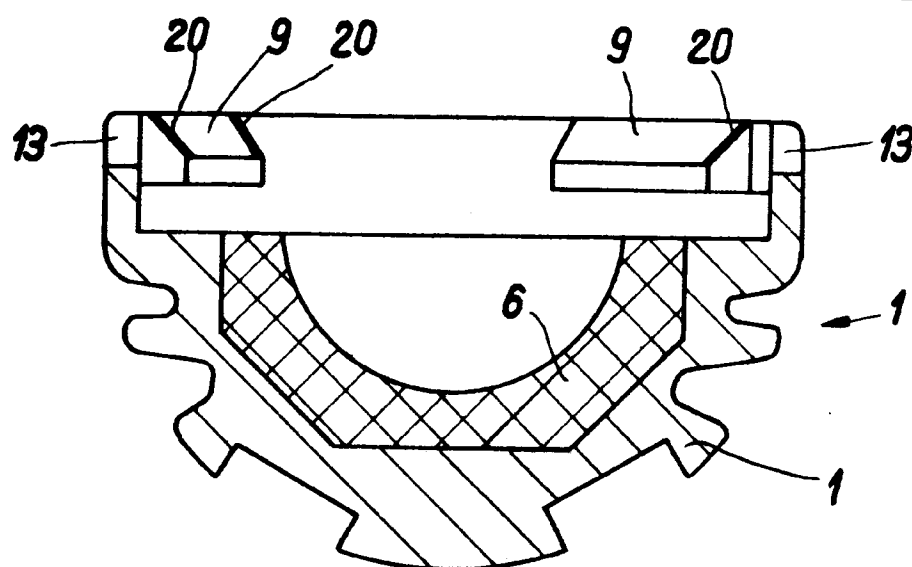


Fig. 4

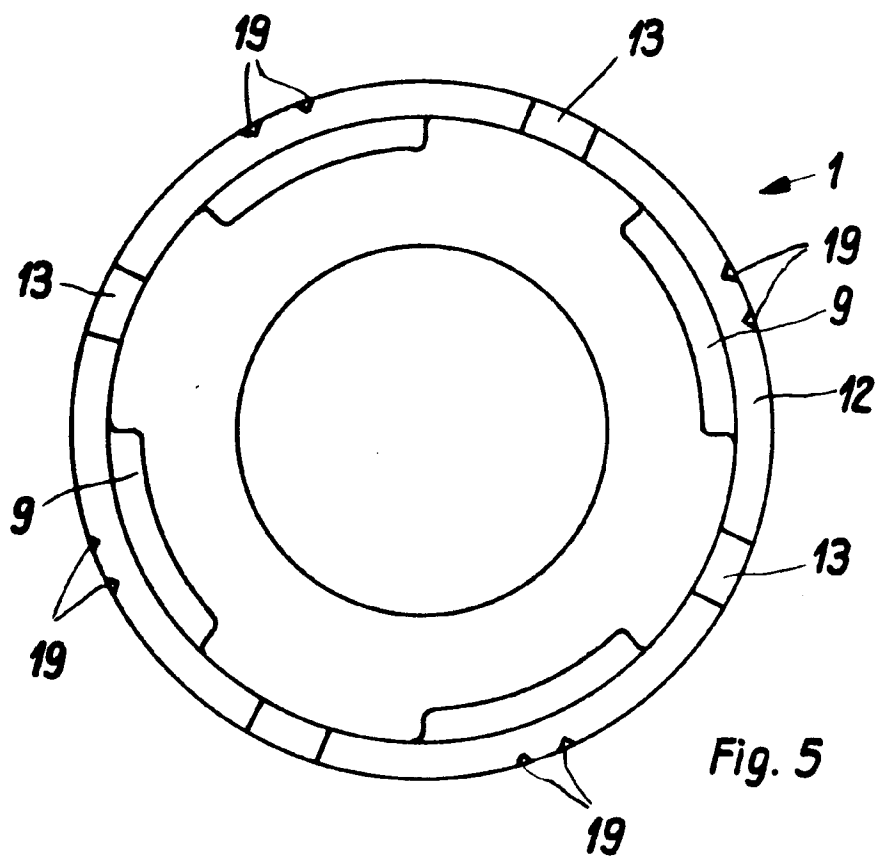


Fig. 5

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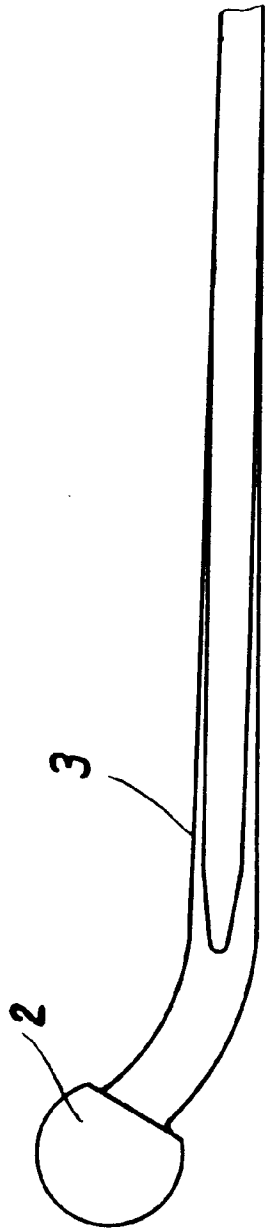


Fig. 6

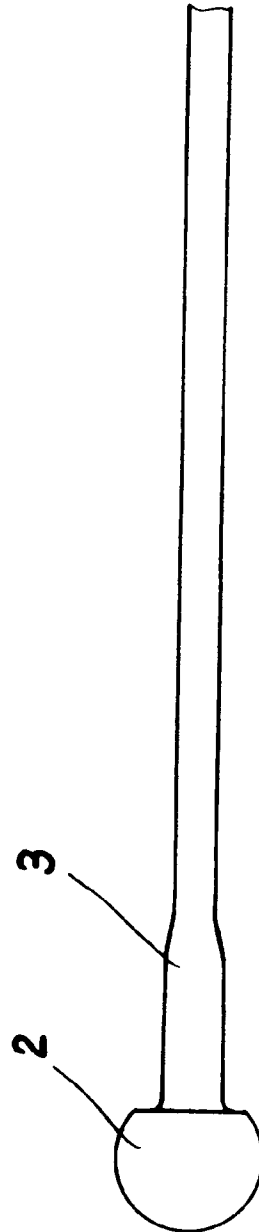


Fig. 7



DEUTSCHES
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⑤④ Distanzstück für den prothetischen Wirbelkörperersatz und Werkzeug zum Einsetzen desselben

DE 30 23 942 A 1

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PATENTANWÄLTE

ZUGELASSENE VERTRETER BEIM EUROPÄISCHEN PATENTAMT

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Patentansprüche

1. Distanzstück für den prothetischen Wirbelkörperersatz, dadurch gekennzeichnet, daß es aus zwei in Längsrichtung aneinander beweglich geführten, je ein Stützende (3, 4) bildenden, mit zusammenwirkenden Rasteinrichtungen (9, 10) versehenen Teilen (1, 2) besteht.
2. Distanzstück nach Anspruch 1, dadurch gekennzeichnet, daß die beiden Teile (1, 2) teleskopisch ausgebildet sind.
3. Distanzstück nach Anspruch 2, dadurch gekennzeichnet, daß die die Teleskopführung bildenden Stange (6) und Bohrung (7) eine mit Spiel passende, ovale Querschnittsgestalt haben, so daß sie bei übereinstimmender Lage ihrer längeren Querachsen (8) in Längsrichtung ineinander verschiebbar sind, und daß die Stange (6) in ihrem zentrumsfernen Querschnittsbereich (9) und der die Bohrung (7) bildende Teil (5) in seinem zentrumsnäheren Querschnittsbereich (10) mit

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zusammenwirkenden Vorsprüngen und Ausnehmungen versehen sind, die durch eine relative Drehung der Teile (1, 2) in Rasteingriff überführbar sind.

4. Distanzstück nach Anspruch 3, dadurch gekennzeichnet, daß die zusammenwirkenden Ausnehmungen und Vorsprünge als Gewindegänge (9, 10) ausgebildet sind.
5. Werkzeug zum Einsetzen und Distrahieren des Distanzstücks nach einem der Ansprüche 3 bis 4, dadurch gekennzeichnet, daß ein Zangenschenkel zur unverdrehbaren Verbindung mit einem (2) der beiden Teile und der andere Zangenschenkel zur drehbaren Verbindung mit dem anderen (1) der beiden Teile ausgebildet ist.
6. Werkzeug nach Anspruch 5, dadurch gekennzeichnet, daß es eine Rasteinrichtung (22) zum Festhalten seiner Spreizstellung aufweist.
7. Werkzeug nach Anspruch 6, dadurch gekennzeichnet, daß die Raststellungen des Werkzeugs den möglichen Arretierungsstellungen des Distanzstücks entsprechen.

Beschreibung

Die Erfindung bezieht sich auf Distanzstück für den prothetischen Wirbelkörperersatz. Sie bezieht sich ferner auf ein Werkzeug zum Einsetzen und Distrahieren dieses Distanzstücks.

Es ist bekannt, einen Wirbelkörper durch einen Metallstift zu ersetzen, der mit Knochenzement ummantelt wird, welcher nach der Gestalt des zu ersetzenden Wirbelkörpers modelliert werden kann. Das Auffinden und gegebenenfalls Anpassen sowie das Einsetzen eines Stifts unveränderlicher Länge ist jedoch zeitraubend. Es ist nicht immer möglich, das Distanzstück während der Aushärtezeit des Knochenzementes zu implantieren. Dies ist aber die Voraussetzung für einen guten Verbund zwischen dem metallischen Implantat, dem Knochenzement und dem Knochen.

Der Erfindung liegt daher die Aufgabe zugrunde, ein Distanzstück und ein Werkzeug zur Implantation desselben zu schaffen, das eine optimale Einpassung innerhalb weniger Sekunden gestattet.

Die erfindungsgemäße Lösung besteht darin, daß das Distanzstück aus zwei in Längsrichtung aneinander beweglich geführten, mit zusammenwirkenden Rasteinrichtungen versehenen Teilen besteht, von denen jeder ein Stützende zum Zusammenwirken mit einem benachbarten Wirbelkörper aufweist.

Das erfindungsgemäße Distanzstück kann im zusammengeschobenen Zustand und daher sehr leicht an den Bestimmungsort gebracht werden und dann zur jeweils gewünschten Länge distrahiert werden. Diese Vorgänge können sich sehr rasch abspielen, insbesondere innerhalb der Aushärtezeit von Knochenzement, so daß ein guter Verbund erreicht werden kann.

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Die gegenseitige Führung der beiden Teile des Distanzstücks ist zweckmäßigerweise teleskopisch ausgebildet. Nach einem besonderen Merkmal ist vorgesehen, daß die an dem einen Teil vorgesehene Stange und die an dem anderen Teil vorgesehene Bohrung der Teleskopführung eine mit Spiel passende, ovale Querschnittsgestalt haben, so daß sie bei übereinstimmender Lage ihrer längeren Querachsen in Längsrichtung ineinander verschiebbar sind; dabei ist ferner vorgesehen, daß die Stange in ihrem zentrumsferneren Querschnittsbereich und der die Bohrung bildende Teil in seinem zentrumsnäheren Querschnittsbereich mit zusammenwirkenden Vorsprüngen bzw. Ausnehmungen versehen sind, die durch eine relative Drehung der Teile in Rasteingriff überführbar sind. Zunächst befinden sich die beiden Teile in derjenigen Stellung, in welcher sie in Längsrichtung gegeneinander verschiebbar sind. Sobald sie auf die vorgesehene Länge ausgezogen sind, werden sie in dieser Längeneinstellung arretiert, indem sie relativ zueinander um 90° verdreht werden. Die zusammenwirkenden Vorsprünge und Ausnehmungen sind zweckmäßigerweise als Gewindegänge ausgeführt, weil sie sich so am leichtesten herstellen lassen.

Ein Werkzeug zum Einsetzen und Distrahieren der Distanzstücke zeichnet sich nach der Erfindung dadurch aus, daß ein Zangenschenkel zur unverdrehbaren Verbindung mit einem der beiden Teile und der andere Zangenschenkel zur drehbaren Verbindung mit dem anderen der beiden Teile ausgebildet ist. Dies ermöglicht es, daß der eine der beiden Teile zwecks Arretierung gedreht wird, solange das Distanzstück von der Zange noch gehalten wird, wobei der andere Teil des Distanzstücks durch das Zusammenwirken mit der Zange so festgehalten wird, daß er sich nicht gleichfalls drehen kann.

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Damit das Distanzstück in der gewünschten Längeneinstellung festgehalten wird, ohne daß es ständigen Kraftaufwandes bedarf, ist das Werkzeug zweckmäßigerweise ebenfalls mit einer Rasteinrichtung ausgerüstet.

Wenn die Vorsprünge und Ausnehmungen zur Arretierung des Distanzstücks so ausgebildet sind, daß sie sich jeweils nur in bestimmten Längeneinstellungen des Distanzstücks durch Verdrehung in Eingriff bringen lassen, ist die Rasteinrichtung des Werkzeugs zweckmäßigerweise so ausgebildet, daß jeweils gerade in denjenigen Längeneinstellungen des Distanzstücks einrastet, in denen dieses durch Verdrehung arretierbar ist.

Die Erfindung wird im folgenden näher unter Bezugnahme auf die Zeichnung erläutert, die ein vorteilhaftes Ausführungsbeispiel veranschaulicht. Darin zeigen:

Figur 1 eine perspektivische Gesamtansicht des Distanzstücks mit den Betätigungswerkzeugen in perspektivischer Ansicht;
Figur 2 und 3 eine Endansicht und eine Seitenansicht des einen Teils des Distanzstücks;
Figur 4 und 5 eine Endansicht und eine Seitenansicht des anderen Teils des Distanzstücks und
Figur 6 ein Werkzeug zum Einsetzen und Distrahieren des Distanzstücks.

Das Distanzstück besteht aus den Teilen 1 und 2, von denen jeder ein Stützende bildet, das aus einem Teller 3 und einem Vorsprung 4 besteht, wobei alle diese Teile konzentrisch und coaxial zueinander angeordnet sind.

Der Abschnitt 5 des Teils 1 und der Abschnitt 6 des Teils 2 bilden gemeinsam eine teleskopische Führung, wobei der Abschnitt 5 eine Hülse mit einer Führungsbohrung darstellt, während der Abschnitt 6 eine in dieser Bohrung verschiebbare Stange ist. Sowohl die Bohrung 7 in der Hülse 5 als

auch die Stange 6 haben, wie man am besten in Fig. 2 und 4 sieht, ovale Querschnittsgestalt und bilden eine Passung, die ein leichtes Verschieben der Stange 6 in der Bohrung 7 gestattet, wenn die längeren Querachsen 8 übereinstimmen. Die Stange ist in ihrem zentrumsferneren Querschnittsbereich mit Gewindegängen 9 versehen, während entsprechende Gewindegänge in der Bohrung 7 in deren zentrumsnäheren Bereich bei 10 vorgesehen sind. Wenn man die mit übereinstimmenden Querachsen 8 ineinanderliegenden Teile 5 und 6 gegeneinander um 90° verdreht, so daß die Achsen 8 nunmehr senkrecht zueinander stehen, greifen die Gewindegänge 9 der Stange 6 in die Gewindegänge 10 der Bohrung 7 ein, und arretieren die beiden Teile daher in Längsrichtung.

Zur Festlegung der beiden Achsrichtungen ist konzentrisch innerhalb der Bohrung 7 ein Stift 11 vorgesehen, der in Längsrichtung einen Viertelausschnitt 12 zeigt. Die Stange 6 enthält eine Mittelbohrung 13, deren Durchmesser mindestens so groß ist wie derjenige des Stifts 11 und weist einen von der Bohrungswand nach innen ragenden Anschlagstift 14 auf. Dieser greift, wenn die Stange 6 in die Bohrung 7 eingeschoben ist, in den Viertelausschnitt 12 des Stifts 11 ein. Im Zusammenwirken des Anschlagstifts 14 mit dem Viertelausschnitt 12 werden zwei Endlagen für die Drehbewegung definiert, wobei in der einen Endlage die beiden Querachsen 8 übereinstimmen, während sie in der anderen Endlage senkrecht zueinander stehen. Die erstgenannte Endlage ist diejenige Stellung, in welche die beiden Teile des Distanzstücks frei gegeneinander in Längsrichtung verschiebbar sind, während die andere Endlage die Arretierstellung darstellt. Der Anschlagstift 14 ist nahe dem offenen Ende der Bohrung 13 angeordnet und der Stift 11 in der Bohrung 7 hat im wesentlichen dieselbe Länge wie diese Bohrung, so daß der Anschlagstift 14 und der Viertelausschnitt 12 des Stifts 11 in jeder denkbaren Längseinstellung der beiden Teile 1 und 2 zusammenwirken.

Es kann eine Arretierschraube 15 vorgesehen sein, (Fig. 3), die nach der Verdrehung der beiden Teile 1 und 2 in die Arretierungsstellung angezogen wird, um eine zufällige Entarretierung zu verhindern. Sobald das Distanzstück in Knochenzement eingebettet ist, ist eine lösende Relativbewegung ausgeschlossen.

Der Teil 2 des Distanzstücks enthält nahe dem Teller 3 eine Querbohrung 16, und Teil 1 ist mit einem Schlüssel-sechskant 17 versehen. Das Distanzstück kann daher mit den in Fig. 1 rechts angedeuteten Werkzeugteilen zusammenwirken. Ein Bolzen 18 und eine Gabel 19 befinden sich an den Enden einer in Fig. 6 veranschaulichten Zange, die in Fig. 1 durch den strichpunktierten Pfeil 20 symbolisiert ist. Der Bolzen 18 paßt in die Bohrung 16 des Teils 2 des Distanzstücks, während die Gabel 19 um den Abschnitt 5 unter den Teller 3 des Teils 1 des Distanzstücks fassen kann. Somit kann man mit der in Fig. 6 gezeichneten Zange das Distanzstück in Pfeilrichtung 20 auseinanderziehen. Wenn es die gewünschte Länge erreicht hat, wird der Gabelschlüssel 21 dazu benutzt, mittels der Schlüsselflächen 17 den Teil 1 des Distanzstücks um 90° zu drehen, während der Teil 2 durch das Zusammenwirken des Bolzens 18 mit der Bohrung 16 unverdrehbar festgehalten wird.

Eine Verdrehung der beiden Teile des Distanzstücks ist nur dann möglich, wenn die Gewindegänge des einen Teils den Gewindenuten des anderen Teils in Umfangsrichtung gegenüberstehen. Damit diese Stellungen leicht gefunden werden können, kann die Rasteinrichtung 22 der Zange so ausgebildet sein, daß in jeweils denjenigen Spreizstellungen eine Raststellung hat, in welchen die soeben genannten Bedingungen für die Verdrehbarkeit des Distanzstücks erfüllt sind.

Das Einsatzgebiet des Distanzstücks ist die Brust- und Lendenwirbelsäule. Die Indikation für einen Wirbelkörperersatz ist beispielsweise bei tumorösen Wirbelkörperdestruktionen gegeben. Der Vorteil des Systems ist darin zu sehen,

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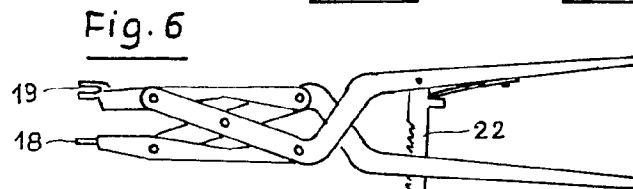
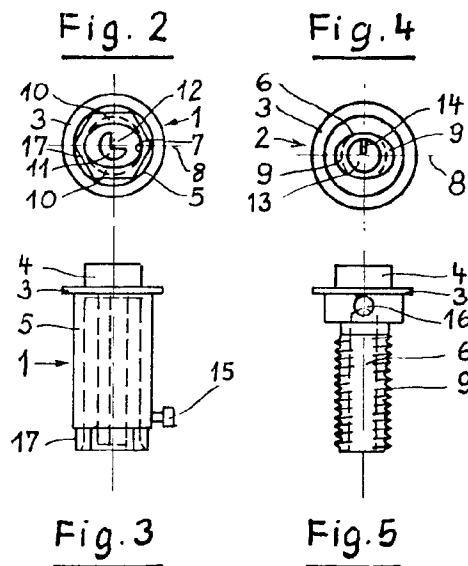
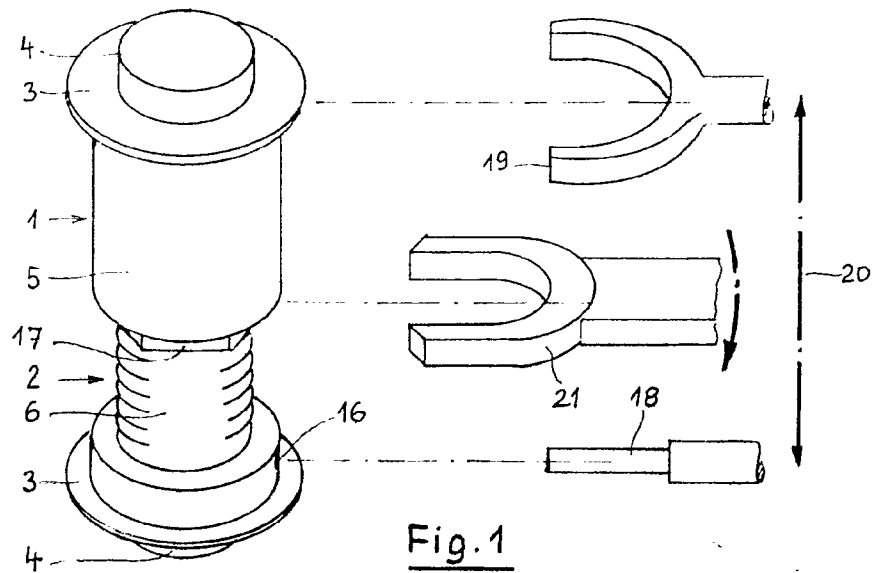
daß eine rasche Implantation und Distraktion möglich ist, was insbesondere bei zusätzlicher Verwendung von Knochenzement von großer Bedeutung ist.

Beispiel:

Eine Hypernephrom-Metastase im 4. BWK führte zu einem beginnenden Querschnitt. Nach rechtsseitiger Thorakotomie und Resektion einer Rippe erfolgte nach Unterbindung der V. azygos die türflügelartige Eröffnung der Pleura und die Ausräumung der Wirbelmetastase unter Mitnahme der proximalen und distalen Zwischenwirbelscheibe. Anschließend wurde in den 3. und 5. Wirbelkörper zentral mit einem gebogenen scharfen Löffel je ein Loch präpariert und das Teleskop-Distanzstück mit der Haltezange probeweise so eingesetzt, daß die Vorsprünge der Stützenden in diese Löcher eingriffen. Unter Bildwandler erfolgte nun die Kontrolle der Lage des Distanzstückes im Verhältnis zu den angrenzenden Wirbelkörpern. Bei gutem Implantatsitz wurde dann eine Schicht Sorbacel als Wärmeschutz zum Rückenmark hin eingebracht. Anschließend wurde der Knochenzement in das proximale und distale Wirbelkörperloch eingebracht. Das Distanzstück wurde vor der Zementaushärtung eingebracht und distrahiert, so daß sich die Zapfen der Stützenden gut in den Wirbelkörpern verankerten. Schließlich wurde der übrige Knochenzement eingebracht und der Wirbelkörper modelliert.

Es ist nicht in allen Fällen erforderlich, Knochenzement zu verwenden. Bei Tumoren mit langsamerem Wachstum besteht die Möglichkeit, autologes Knochenmaterial anstelle von Knochenzement einzusetzen.

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⑬ BUNDESREPUBLIK
DEUTSCHLAND



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in Betracht zu ziehende Druckschriften:
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㉖ Zwischen zwei Knochen einsetzbares Stützelement

Ein zwischen zwei Knochen einsetzbares Stützelement besteht aus einer äußeren Hülse und einem darin einsetzbaren mit einem Fluid gefüllten Balg, der im eingesetzten und gefüllten Zustand über beide Stirnseiten der Hülse hinausragt. Ein derartiges Stützelement ist einfach aufgebaut und schmiegt sich gut an unebene Flächen an.

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Beschreibung

Die Erfindung betrifft ein zwischen zwei Knochen einsetzbares Stützelement.

Der Erfindung liegt die Aufgabe zugrunde, ein derartiges Stützelement zu schaffen, das einfach aufgebaut ist und gut an unebenen Flächen anliegt. Erfindungsgemäß wird diese Aufgabe durch Anwendung der Maßnahmen des Kennzeichens des Anspruchs 1 gelöst.

Da sich das erfindungsgemäße Stützelement an die festen Flächen der Knochen anschmiegt, tritt an diesen Stellen keine Reibung auf, die zu Schmerzen führen kann.

Zwei Ausführungsbeispiele der Erfindung sind anhand der Zeichnung beschrieben. Es zeigt, jeweils in einer Ansicht

Fig. 1 die Hülse eines ersten Ausführungsbeispiels,

Fig. 2 den darin einsetzbaren Balg,

Fig. 3 die Hülse eines zweiten Ausführungsbeispiels und

Fig. 4 den darin einsetzbaren Balg.

Das Ausführungsbeispiel gemäß **Fig. 1** und **2** weist eine Hülse **1** mit einem in Längsrichtung verlaufenden Schlitz **2** auf. Die Hülse besteht aus einem körperverträglichen, federnden Material, beispielsweise Metall oder Kunststoff. Zum Einsatz in die Hülse **1** ist ein Balg **3** mit vorgesehen. Dieser weist einen in Längsrichtung verlaufenden Schlitz **4** sowie eine zentrale Durchtrittsöffnung **8** auf. Der Balg **3** besteht aus einer vorgeformten, der Innenform der Hülse **1** angepaßten Hülse **5**, aus einem flexiblen, unelastischen Material, beispielsweise einer Kunststoffolie, und ist mit einem Fluid **6**, vorzugsweise einer Flüssigkeit, beispielsweise einer physiologischen Kochsalzlösung oder einem Siliconöl, gefüllt.

Die axiale Länge *a* des Balges **3** ist etwas größer gewählt als die axiale Länge *b* der Hülse **1**, so daß der Balg **3** nach Einsatz in die Hülse **1** über deren beide Stirnseiten **7** etwas hinausragt.

Das erfindungsgemäße Stützelement kann anstelle eines Wirbelknochens eingesetzt werden. Dann wird zunächst der Balg **3** um das Rückenmark im Bereich des entfernten Wirbelknochens herumgelegt. Anschließend wird die aus federndem Material bestehende Hülse **1** über den Balg **3** geschoben. Die Hülse **1** verhindert dann ein Zusammendrücken des Balges **3** in Längsrichtung.

Beim Ausführungsbeispiel gemäß **Fig. 3** und **4** ist eine Hülse **10** aus einem federnden Material vorgesehen. Die Hülse **10** umfaßt ein Mittelstück **11**, dessen beide Enden in je einen Rand **12** größeren Durchmessers übergehen. Die Hülse **10** weist einen in Längsrichtung verlaufenden Schlitz **13** auf.

Zum Einsatz in die Hülse **10** ist ein Balg **14** bestimmt, der aus einem flexiblen, nicht elastischen Werkstoff, wie beispielsweise einer Kunststoffolie, hergestellt und mit einem Fluid gefüllt ist. Der Balg **14** ist der Innenform der Hülse **10** angepaßt und weist hierzu um eine zentrale Durchtrittsöffnung **15** ein Mittelstück **16** auf, das in zwei Randabschnitte **17** mit größerem Außendurchmesser übergeht. Der Balg **14** weist außerdem einen in Längsrichtung verlaufenden Schlitz **18** auf. Bei dieser Ausführungsform ist die Höhe *c* der Randabschnitte **17** größer bemessen als die innere Höhe *d* des Randes **12** der Hülse **10**. Hierdurch ist eine axiale Bewegung des Balges **14** gegenüber der Hülse **10** verhindert. Ist der Balg **14** in die Hülse **11** eingesetzt, so ragen daher die Randabschnitte **17** wiederum über den Rand **12** hinaus.

Die Erfindung ist nicht auf die dargestellten Ausführungsbeispiele beschränkt. Insbesondere können die

Hülse und der Balg anstelle einer zylindrischen Querschnittsform auch eine polygonale Querschnittsform aufweisen. Auch ist es möglich bei Ausbildung der Hülse nach **Fig. 1** einen Balg der in **Fig. 4** gezeigten Form zu verwenden.

Weiterhin besteht die Möglichkeit, den Balg statt mit einer Flüssigkeit auch mit einem Gas zu füllen. Hierdurch kann eine weichere Abstützung erreicht werden. Die mit dem Stützelement zu übertragende Stützkraft ist jedoch aufgrund der Gaskompressibilität geringer.

Patentansprüche

1. Zwischen zwei Knochen einsetzbares Stützelement, **dadurch gekennzeichnet**, daß das Stützelement aus einer äußeren Hülse (**1**, **10**) und einem darin einsetzbaren, mit einem Fluid (**6**) gefüllten Balg (**3**, **14**) aus einem flexiblen, unelastischen Material besteht, der im eingesetzten und gefüllten Zustand über beide Stirnseiten der Hülse (**1**, **10**) hinausragt.
2. Stützelement nach Anspruch 1, **dadurch gekennzeichnet**, daß der Balg (**3**, **14**) eine in Längsrichtung verlaufende, zentrale Durchtrittsöffnung (**8**, **15**) aufweist.
3. Stützelement nach Anspruch 1 oder 2, **dadurch gekennzeichnet**, daß die aus federndem Material hergestellte Hülse (**1**, **10**) und der Balg (**3**, **14**) je einen in Längsrichtung verlaufenden Schlitz (**2**, **4**, **13**, **18**) aufweisen.
4. Stützelement nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet**, daß die Hülse (**10**) ein Mittelstück (**11**) aufweist, an dessen beiden Enden je ein Rand (**12**) größeren Durchmessers versehen ist.
5. Stützelement nach Anspruch 4, **dadurch gekennzeichnet**, daß der Balg (**14**) ein Mittelstück (**16**) aufweist, an dessen beiden Enden je ein Randabschnitt größeren Durchmessers vorgesehen ist, der dem Innendurchmesser des Randes (**12**) der Hülse (**10**) angepaßt ist.
6. Stützelement nach Anspruch 1, **dadurch gekennzeichnet**, daß als Fluid eine Flüssigkeit (**6**), wie eine physiologische Kochsalzlösung oder ein Siliconöl, Verwendung findet.

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Fig. 1

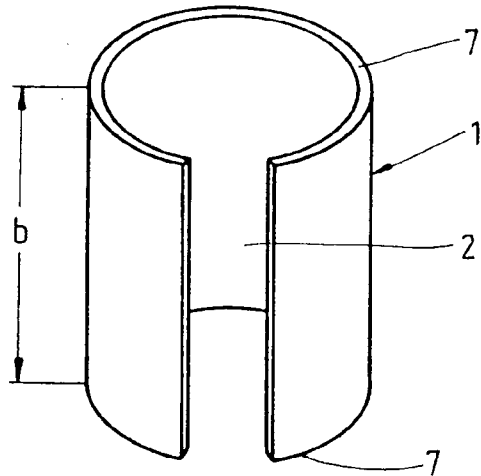


Fig. 2

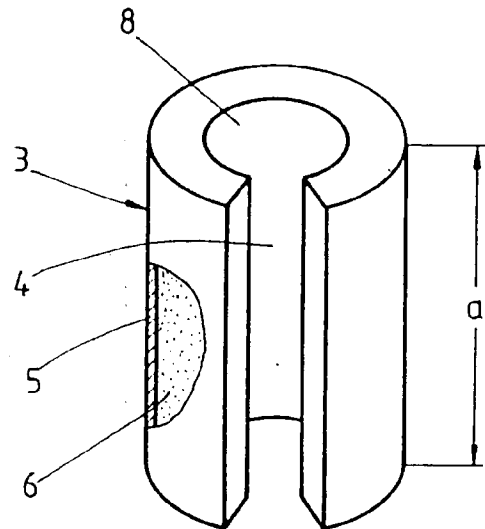


Fig. 3

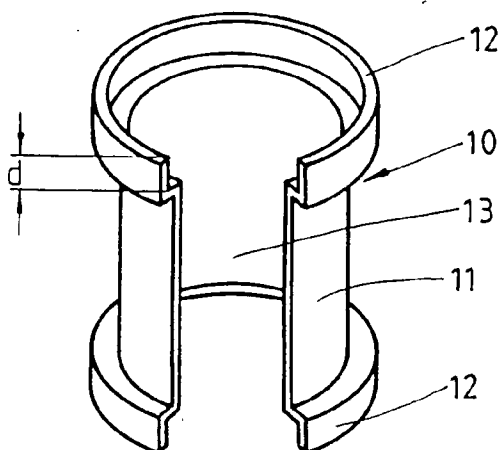
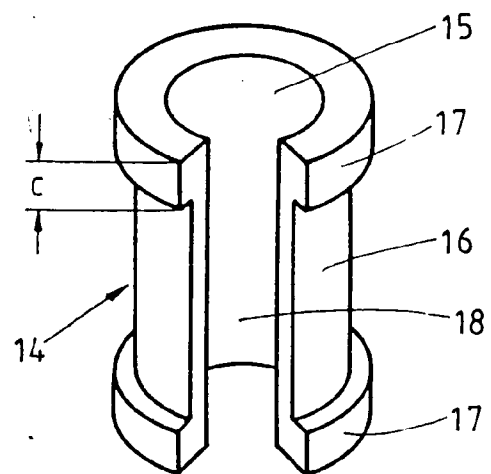


Fig. 4





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56 Für die Beurteilung der Patentfähigkeit
in Betracht gezogene Druckschriften:

DE	37 29 600 C3
DE	30 23 942 C3
DE	29 51 251 C2
DE	36 20 549 A1

54 Wirbelkörperimplantat

- 57 Es wird ein Wirbelkörperimplantat aus Metall für die
Implantation in der menschlichen Wirbelsäule beschrieben.
Das Implantat kann als Ersatz für einen Wirbelkörper oder
aber als Implantat für die Fusion zweier Wirbelkörper
ausgebildet sein.

Es besteht mindestens aus einem ersten Teil und einem
zweiten Teil. Das erste Teil ist in einer Richtung gegen das
zweite Teil verschieblich. Die Bewegung des ersten Teils
gegenüber dem zweiten Teil in die Gegenrichtung ist durch
eine unmittelbar oder mittelbar zwischen den Teilen wirken-
de Verrastung zweier Zahnleisten blockierbar. Zwischen den
Teilen ist mindestens ein elastisches Polster vorgesehen,
welches im nichtimplantierten Zustand des Implantats vor-
gespannt ist und einen federnden Eingriff der Zahnleisten
bewirkt. Es ist ein Dauer-Arretierungsmittel vorgesehen,
welches beide Teile miteinander im implantierten Zustand
verspannt.

DE 40 12 622 C 1

Die Erfindung betrifft ein Wirbelkörperimplantat aus Metall für die Implantation in der menschlichen Wirbelsäule. Hierbei dient es je nach Indikation und dementsprechender Ausführungsform zum Ersatz eines Wirbelkörpers oder zur Fusion zweier Wirbelkörper.

Es ist ein Wirbelkörperimplantat in Form eines sogenannten Keystone-Implantats bekannt. Dieser einstückige Metallblock dient zur ventralen Fusion zweier Wirbelkörper (DE 36 20 549 A1).

Entsprechend den individuellen Patienten-Erfordernissen ist es notwendig, eine Vielzahl derartiger Implantate unterschiedlicher Größe herzustellen und beispielsweise in der Klinik auf Lager zu halten. Dies verteuert die Herstellung und Verwendung des bekannten Implantats beträchtlich.

In ihrer Länge verstellbare Implantate sind aus der DE 37 29 600 C2 und der DE 30 23 942 C3 bekannt. Die erstgenannte Druckschrift zeigt ein Implantat, das aus zwei Teilen, einem caudalen und einem kranialen Teil, besteht. An einem Teil ist eine sich in Richtung auf das andere Teil erstreckende Führungshülse mit einem Außengewinde vorgesehen. Das andere Teil weist einen in der Führungshülse verschiebbaren Führungsstab mit ebenfalls einem Außengewinde auf. Die Verbindung zwischen beiden Teilen wird durch eine Mutter hergestellt, die auf einer Seite eine Gewindebohrung entsprechend dem Außengewinde auf dem Führungsstab und auf der anderen Seite eine Gewindebohrung entsprechend dem Außengewinde der Führungshülse aufweist. Die Längeneinstellung des Implantats erfolgt durch Verschiebung des Führungsstabs in der Führungshülse. Sie wird durch Anziehen der Mutter fixiert.

Dieses Implantat läßt sich nur sehr ungenau einstellen. Insbesondere ist es praktisch unmöglich, die Längeneinstellung direkt am Ort der Implantation vorzunehmen, da erst in umständlicher Weise die einmal eingestellte Länge durch Anziehen der Mutter fixiert werden müßte.

Aus der DE 30 23 942 C2 ist ein zweistückiges Implantat bekannt, welches wie das vorbeschriebene an einem Teil eine Hülse und am anderen Teil eine Führungsstange aufweist, die in der Hülse längsverschieblich gelagert ist, um die Länge des Implantats einstellen zu können. Die Stange und die Hülse weisen Rasteinrichtungen, beispielsweise nur auf Teilen ihrer Peripherie zusammenwirkende Gewindegänge, auf, mit denen nach Einstellung der gewünschten Länge des Implantats die beiden Teile in Rasteingriff gebracht werden können, und zwar durch Verdrehen der Teile gegeneinander. Das Implantat soll im zusammengeschobenen Zustand an den Ort der Implantation gebracht werden können, wo es auf die gewünschte Länge distrahiert werden soll. Dazu müssen sich die beiden Teile in der Stellung befinden, in der sie in Längsrichtung gegeneinander verschiebbar sind. Sie nehmen also nicht ihre Rasteinstellung ein. Nun herrschen aber in der Wirbelsäule erhebliche Kräfte, die beim Einsetzen eines Implantats zunächst einmal überwunden werden müssen. Damit das erwähnte Implantat in seinem längsverschiebbaren Zustand nicht aufgrund der erwähnten Kräfte einfach in seine Lage geringsten Ausmaßes zurückgedrängt wird, ist in der besagten Druckschrift eine Spezialzange erwähnt, mit der das Implantat auseinander gespreizt werden kann und schließlich das eine Teil gegen das andere in die Raststellung verdreht werden kann.

Davon abgesehen, daß die gesamte Handhabung dieses Implantats sehr umständlich ist, muß in situ ein Teil gegen das andere verdreht werden, wodurch die exakte Position des Implantats in der Wirbelsäule nicht vorherbestimmbar ist. Bedenkt man weiterhin die erwähnten Kompressionskräfte in der Wirbelsäule, kann nicht ausgeschlossen werden, daß das ganze Implantat bei der auszuführenden Drehung des einen Teils aus seiner Lage in der Wirbelsäule herausgedreht wird im Wege einer Ausgleichsbewegung. Diese Nachteile sind aus heutiger Sicht nicht mehr tragbar.

Im Bereich von Körperimplantaten ist im übrigen die Verwendung von Zahnleisten als Rasteinrichtungen für eine Längeneinstellung eines aus mehreren Teilen bestehenden Implantats bekannt. So zeigt die DE 29 51 251 C2 eine Gelenkbandendoprothese, die eine am Knochen befestigbare Platte sowie als Gegenstück eine plattenförmige Verbindungseinrichtung aufweist. Beide Teile sind jeweils mit zueinander zugekehrten Zahnleisten versehen, mit deren Hilfe die Teile nach Einstellung der gewünschten Position verrastbar sind. Die Dauerarretierung erfolgt mittels einer die Teile durchdringenden Knochenschraube.

Aufgabe der vorliegenden Erfindung ist es vor diesem Hintergrund, ein Wirbelkörperimplantat der vorerwähnten Art so weiterzubilden, daß es einfach und sicher handhabbar ist.

Gelöst wird diese Aufgabe durch ein Wirbelkörperimplantat mit den Merkmalen des kennzeichnenden Teils des Anspruchs 1.

Es wird unterschieden zwischen Implantaten zum Ersatz eines Wirbelkörpers einerseits und Implantaten zur Fusion zweier Wirbelkörper andererseits. Beiden Implantatarten ist zur Lösung der angegebenen Aufgabe gemeinsam, daß die Verrastung zwischen dem ersten Teil und dem zweiten Teil durch zwei Zahnleisten, die durch wenigstens ein zwischen dem ersten und dem zweiten Teil angeordnetes elastisches Polster vorgespannt sind und nur in einer Richtung gegeneinander bewegbar sind, wirkt.

Durch Verschiebung des ersten Teils gegenüber dem zweiten Teil kann die Größe bzw. Länge des Implantats individuell in situ eingestellt werden. Damit beide Teile im expandierten Zustand des Implantats nicht ohne weiteres aufgrund der in der Wirbelsäule herrschenden Kräfte während der Implantation wieder in die entgegengesetzte Richtung gleiten können, also in den kontrahierten Zustand gelangen, ist als Sicherungsmaßnahme vorgesehen, daß zwischen beiden Teilen mittelbar oder unmittelbar eine Verrastung zwischen den Zahnleisten wirkt, so daß die Bewegung des ersten Teils gegenüber dem zweiten Teil in die erwähnte Richtung blockiert ist. Zwischen den Teilen ist mindestens ein elastisches Polster vorgesehen, das bereits im nichtimplantierten Zustand des Implantats für einen federnden Eingriff der Zahnleisten sorgt. Diese Maßnahme gewährleistet, daß die Teile vor und während der Implantation kontrolliert zueinander positioniert werden können, wobei die erwähnte Verrastung bereits in diesem Zustand zum Tragen kommt. Zur Expansion des Implantats wird das erste Teil gegen das zweite Teil unter kurzzeitiger Aufhebung der erwähnten federnden Verrastung gegen die federnde Wirkung des oder der elastischen Polster um ein oder mehrere Zahnelemente der Zahnleisten verschoben, woraufhin aufgrund der durch das Polsterelement erzeugten Vorspannung die Verrastung sofort wieder hergestellt wird, so daß eine Bewegung der Teile zueinander in die Gegenrichtung unter-

bunden wird.

In der Ausbildung des erfindungsgemäßen Wirbelkörperimplantats als Wirbelkörperersatz weist das erste Teil einen im wesentlichen T-förmigen Querschnitt und das zweite Teil einen im wesentlichen U-förmigen Querschnitt auf, in dessen Ausnehmung der Steg des ersten Teils eingeführt werden kann, wobei die eine der für die Verrastung notwendigen Zahnleiste außen auf einer Seite am Steg des ersten Teils und die andere der Zahnleisten an der Innenseite eines Schenkels des zweiten Teils vorgesehen ist, wobei das elastische Polster zwischen der anderen Seite des Stegs und der Innenseite des anderen Schenkels angeordnet ist.

Vorzugsweise ist der im wesentlichen U-förmige Querschnitt des zweiten Teils im Bereich der Basis des "U" erweitert, so daß sich die Ausnehmung als Trapez darstellt. Diese Maßnahme gestattet während der Implantation eine Aufhebung der Verrastung beider Teile in dem Falle, daß das Implantat zu weit expandiert worden ist. Hierzu wird das erste Teil in der Ausnehmung des zweiten Teils leicht gekippt, so daß die Zahnleisten außer Eingriff kommen und das erste Teil in Richtung der Basis der Ausnehmung des zweiten Teils gebracht werden kann, woraufhin das erwähnte elastische Polster dafür sorgt, daß die Zahnleisten wieder unter federnden Eingriff gelangen.

Das erwähnte Dauer-Arretierungsmittel kann gebildet sein aus einer in einem Schenkel des zweiten Teils vorgesehenen Längsbohrung, durch welche eine Schraube in eine Bohrung in dem Steg des ersten Teils greift. Für die Arretierung wird die Schraube fest angezogen.

Als Dauer-Arretierungsmittel ist auch eine in einem Schenkel vorgesehene Nut möglich, in die ein abgeflachter Rundstift setzbar ist. Wenn die durch Drehung des Stifts in die Ausnehmung ragende Rundung in Anlage mit dem Steg des ersten Teils kommt, wird dieser dauerhaft in der Ausnehmung des zweiten Teils gespannt.

Das oder die elastischen Polster können bei der beschriebenen Ausführungsform als in die Ausnehmung des zweiten Teils ragende und an diesem befestigte sterilisierbare Silikon-Körper sein. Denkbar wäre beispielsweise auch eine Verwendung einer Blattfeder, um den gewünschten Effekt zu erzielen.

Die Zahnleiste an der Innenseite der Ausnehmung eines Schenkels des zweiten Teils und an der Außenseite des Stegs des ersten Teils weisen vorteilhaft Zähne auf, deren Zahnflanken in Richtung der zulässigen Bewegung, d. h. in Expansionsrichtung des Implantats einen Anstiegswinkel zu dieser Richtung von etwa 30° aufweisen und deren abfallende Zahnflanken etwa senkrecht auf der genannten Richtung stehen. Der Anstiegswinkel gestattet ein relativ leichtes Verschieben der Teile zueinander, während der Abfallwinkel von ca. 90° mit großer Sicherheit für ein Blockieren einer Bewegung in Gegenrichtung sorgt.

In einer Ausführungsform des erfindungsgemäßen Implantats als Implantat zur ventralen Fusion zweier Wirbelkörper weist das erste Teil an der Innenseite eine keilförmige Aussparung auf, in der ein keilförmiger Gleitblock in eine Richtung verschieblich gelagert ist, die im wesentlichen senkrecht auf der Expansionsrichtung des Implantats steht. Der Gleitblock ist auf der zu dem zweiten Teil gerichteten Seite mit einer Zahnleiste versehen, die mit der anderen Zahnleiste auf der Innenseite des zweiten Teils verrastbar ist, wobei das elastische Polster zwischen der Wand der keilförmigen Aus-

nehmung und der Seite des Gleitblocks angeordnet ist, die zum ersten Teil gerichtet ist. Bei dieser Ausführungsform wirkt die Verrastung zwischen dem ersten Teil und dem zweiten Teil mittelbar über den erwähnten Gleitblock.

Während der Implantation kann beispielsweise über ein Getriebemechanismus, beispielsweise über ein Schneckengetriebe, der Gleitblock in die vorgesehene Richtung bewegt werden. Dabei sorgen wiederum die elastischen Polster für einen federnden Eingriff der Zahnleisten bereits im nichtimplantierten Zustand des Implantats.

Diese Ausführungsform ist vorteilhaft so weitergebildet, daß das erste Teil mit zwei an ihm befestigten, in horizontaler Richtung weisenden Führungsstiften versehen ist, welche in zwei entsprechenden Führungskanälen im zweiten Teil geführt sind, wobei die Führungsstifte zusammen mit den Führungskanälen die maximale Strecke der zulässigen Bewegung in horizontaler Richtung begrenzen.

Die Führungskanäle können in einer besonders einfachen Ausführung Stufenbohrungen sein. In diesem Falle können die Führungsstifte in diese Bohrung setzbare Zylinderkopfschrauben mit jeweils einem gewindelosen Schaft im Kopfbereich (Dünnschaft-Schrauben) und einem Gewinde sein, das in entsprechende Gewindebohrungen im ersten Teil schraubbar ist. Dabei bilden die erwähnten Schrauben gleichzeitig die Dauer-Arretierungsmittel des Implantats.

Bei der vorerwähnten Ausführungsform weisen die Zahnflanken der Zahnleisten in der Gleitrichtung des Gleitblocks zu dieser einen Anstiegswinkel im Bereich von 30° auf. Die abfallenden Zahnflanken stehen dagegen im wesentlichen senkrecht auf der erwähnten Richtung. Hier gestattet der Anstiegswinkel wiederum ein relativ leichtes Verschieben des Gleitblocks in dessen Gleitrichtung, wohingegen der erwähnte Abfallwinkel von etwa 90° eine große Sicherheit gegen ein Zurückgleiten des Gleitblocks zwischen dem caudalen und dem kranialen Teil bietet.

Die Erfindung wird anhand zweier Ausführungsbeispiele anhand der Zeichnung näher erläutert.

Hierbei zeigt

Fig. 1 eine perspektivische Ansicht der Teile eines Wirbelkörperimplantats als Wirbelkörperersatz,

Fig. 2 eine Schnittansicht des Implantats gemäß Fig. 1,

Fig. 3 eine perspektivische Ansicht der Teile eines Wirbelkörperimplantats zur ventralen Fusion zweier Wirbelkörper gemäß einer Ausführungsform,

Fig. 4 eine Schnittansicht des Implantats nach Fig. 3, und

Fig. 5 eine Prinzipansicht zweier verwendeter Zahnleisten.

Nachfolgend sind gleiche Teile mit denselben Bezugszeichen versehen.

In den Fig. 1 und 2 ist ein erstes Ausführungsbeispiel eines erfindungsgemäßen Wirbelkörperimplantats dargestellt, das als Wirbelkörperersatz ausgebildet ist.

Das erste Teil 1 weist einen im wesentlichen T-förmigen Querschnitt auf.

Eine Zahnleiste 3 mit Zähnen 5 ist außen am Steg 11 vorgesehen. Auf seiner oberen Seite ist das Teil 1 mit einem metallischen offenzelligen Belag 8 versehen.

Das zweite Teil 2 weist ventral gesehen einen im wesentlichen U-förmigen Querschnitt auf, in dessen leicht trapezförmige Ausnehmung 10 der Steg 11 des ersten Teils 1 einführbar ist. An der Innenseite des einen

Schenkels 13 des Teils 2 ist eine Zahnleiste 4 vorgesehen, die mit der Zahnleiste 3 des Teils 1 verrastbar ist. Am gegenüberliegenden Schenkel 12 sind zwei in die Ausnehmung 10 ragende elastische Polster 30, beispielsweise aus Silikon, befestigt.

Eine Längsnut 32 im Schenkel 12 des zweiten Teils 2 bildet zusammen mit einem in diese einsetzbaren abgeflachten Rundstift 31 das Dauer-Arretierungsmittel in dem gezeigten Ausführungsbeispiel.

Auf der unteren Seite ist das zweite Teil 2 mit einem offenzelligen metallischen Belag 8 versehen.

Eine Ausnehmung 35 in der Basis des zweiten Teils 2 bietet eine Angriffsmöglichkeit für ein (nicht dargestelltes) Werkzeug, um die Verrastung der Zahnleisten 3, 4 erforderlichenfalls zu lösen, etwa wenn das erste Teil 1 zu weit aus dem zweiten Teil bewegt worden ist.

Beim Einführen des Stegs 11 in die Ausnehmung 10 werden die Polster 30 zusammengedrückt und dementsprechend unter Vorspannung gesetzt, so daß die Zahnleisten 3, 4 in federnden Eingriff kommen. Während der Implantation wird der Stift 31 in der Nut 32 so gedreht, daß sein abgeflachtes Segment zur Ausnehmung 10 hingewandt ist. Der Operateur wird das erste Teil 1 mit einem Werkzeug (nicht dargestellt) gegenüber dem zweiten Teil in die Expansionsrichtung X in situ solange verschieben, bis das Implantat die erforderliche Länge erreicht hat. Die Bewegung wird dadurch ermöglicht, daß die Zahnleisten 3 und 4, wie in Fig. 5 dargestellt, Zähne 5 aufweisen, deren Zahnflanken 6 einen Anstiegswinkel in Richtung X der Bewegung von etwa 30° zu dieser und deren abfallende Zahnflanken 7 einen Abfallwinkel von etwa 90° zur Richtung X aufweist. Der Anstiegswinkel von etwa 30° ermöglicht eine relativ leichte Bewegung des ersten Teils 1 gegenüber dem zweiten Teil 2 unter kurzzeitiger Aufhebung des federnden Eingriffs der Zahnleisten 3, 4. Nach Erreichen der nächsten Zahnreihe kommen die Zahnleisten 3, 4 wieder in einen federnden Eingriff.

In die Gegenrichtung X ist das erste Teil 1 aufgrund der Ausbildung der Zähne 5 im beschriebenen Sinne nicht ohne weiteres möglich. Lediglich durch ein Ansetzen eines Werkzeugs in der Ausnehmung 35 kann ein Verschwenken des ersten Teils 1 in der trapezförmigen Ausnehmung 10 des Teils 2 erreicht werden mit der Wirkung, daß die Zahnleisten 3, 4 außer Eingriff kommen und das erste Teil 1 in Richtung X versetzt werden kann. Letzteres wird — wie bereits erwähnt — nur dann erforderlich sein, wenn das Teil 1 zu weit aus der Ausnehmung 10 gezogen worden ist.

Nach Einstellung der gewünschten Größe oder Länge des Implantats wird der Stift 32 so verdreht, daß sein runder Abschnitt in die Ausnehmung 10 ragt und in Anlage mit dem Schenkel 11 des ersten Teils 1 gelangt, wie dies in Fig. 2 dargestellt ist. Auf diese Weise kann eine dauerhafte Arretierung beider Teile 1, 2 vorgenommen werden.

In den Fig. 3 und 4 ist als weiteres Ausführungsbeispiel des erfindungsgemäßen Wirbelkörperimplantats eine erste Ausführungsform des Implantats für die ventrale Fusion zweier Wirbelkörper dargestellt.

Das erste Teil 1 weist eine keilförmige Aussparung 17 auf. In dieser ist ein keilförmiger Gleitblock 18 in der Richtung Y verschieblich gelagert. Auf seiner Basis ist der Gleitblock 18 mit einer Zahnleiste 3 versehen, die einer Zahnleiste 4 auf der Innenseite des zweiten Teils 2 entspricht und mit dieser verrastbar ist.

Ein elastisches Polster 30 in der keilförmigen Aussparung 17 des ersten Teils 1 sorgt nach dem Zusammen-

bau der Teile 1, 2 und 18 für einen federnden Eingriff der Zahnleisten 3, 4.

Als Dauer-Arretierungsmittel sind hier zwei Dünnschaftschrauben 20, 21 vorgesehen, die durch jeweils eine Stufenbohrung 22, 23 im zweiten Teil 2 hindurch in zwei entsprechend angeordneten Gewindebohrungen 33, 34 im ersten Teil verschraubbar sind.

Die Schrauben 20, 21 bilden in die Richtung X der zulässigen Bewegung, also in Expansionsrichtung des Implantats, weisende Führungsstifte. Die Stufenbohrungen 22, 23 bilden dabei Führungskanäle. Durch die Tiefe der Stufenbohrungen 22, 23 läßt sich demnach die maximale Expansionsbewegung des ersten Teils 1 gegenüber dem zweiten Teil 2 begrenzen.

Die Zahnleisten 3, 4 sind vorliegend so ausgebildet, daß die Zahnflanken ihre Zähne in Richtung Y, also in Richtung der zulässigen Bewegung des Gleitblocks 18, einen Anstiegswinkel zu dieser Richtung Y im Bereich von 30° aufweisen, während die abfallenden Zahnflanken im wesentlichen senkrecht auf der Richtung Y stehen. Hierdurch wird die Bewegung des Gleitblocks 18 in Richtung Y ermöglicht, in der Gegenrichtung Y aber sicher blockiert.

Die Verrastung zwischen dem ersten Teil 1 und dem zweiten Teil 2 wirkt vorliegend mittelbar durch den Gleitblock 18. Es ist verständlich, daß mit zunehmender Bewegungsstrecke des Gleitblocks 18 in Richtung Y sich das erste Teil 1 in Richtung X bewegt. Ermöglicht werden kann dies beispielsweise durch ein an den Gleitblock 18 angreifendes (nicht dargestelltes) Schneckengetriebe.

Allen im Rahmen der Erfindung beanspruchten Wirbelkörperimplantate ist gemeinsam, daß mit einer zwischen dem ersten und dem zweiten Teil des Implantats wirkenden Verrastung für eine große Sicherheit gegen ein Verrutschen des einen gegenüber dem anderen Teil gesorgt ist, eine individuelle Einstellung auf die Patientenfordernisse aufgrund der Ausbildung der Zahnleisten aber dennoch möglich ist.

Patentansprüche

1. Wirbelkörperimplantat aus Metall, welches mindestens aus einem ersten Teil und aus einem zweiten Teil besteht, welche zueinander verschieblich und in ihrer gewünschten Endlage miteinander durch eine Verrastung festlegbar sind, und welches ein Dauerarretierungsmittel aufweist, welches beide Teile im implantierten Zustand dauerhaft miteinander verspannt, **dadurch gekennzeichnet**, daß die Verrastung zwischen dem ersten Teil (1) und dem zweiten Teil (2) durch zwei Zahnleisten (3, 4), die durch wenigstens ein zwischen dem ersten und dem zweiten Teil (1, 2) angeordnetes elastisches Polster (30) vorgespannt sind und nur in einer Richtung (x) gegeneinander bewegbar sind, wirkt.
2. Wirbelkörperimplantat als Wirbelkörperersatz nach Anspruch 1, dadurch gekennzeichnet, daß das erste Teil (1) einen T-förmigen Querschnitt und das zweite Teil (2) einen U-förmigen Querschnitt aufweist, in dessen Ausnehmung (10) der Steg (11) des ersten Teils (1) einführbar ist, daß die eine der Zahnleisten (3) außen auf einer Seite am Steg (11) des ersten Teils (1) und die andere der Zahnleisten (4) an der Innenseite eines Schenkels (13) des zweiten Teils (2) vorgesehen ist und daß das elastische Polster (30) zwischen der anderen Seite des Stegs (11) und der Innenseite des anderen Schenkels (12)

angeordnet ist.

3. Wirbelkörperimplantat nach Anspruch 2, dadurch gekennzeichnet, daß das Dauer-Arretierungsmittel gebildet ist aus einer in dem Schenkel (12) des ersten Teils (1) vorgesehenen Längsbohrung, durch welche eine Schraube in eine Bohrung in dem Steg (11) des zweiten Teils (2) greift. 5

4. Wirbelkörperimplantat nach Anspruch 2 oder 3, dadurch gekennzeichnet, daß die elastischen Polster (30) in die Ausnehmung (10) des ersten Teils (1) ragende und an diesem befestigte, sterilisierbare Silikonkörper sind. 10

5. Wirbelkörperimplantat nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Zahnleisten (3, 4) Zähne (5) aufweisen, deren Zahnflanken (6) in Richtung (x) der zulässigen Bewegung einen Anstiegswinkel zur Richtung (x) von etwa 30° aufweisen und deren abfallende Zahnflanken (7) etwa senkrecht auf der Richtung (x) der zulässigen Bewegung stehen. 15 20

6. Wirbelkörperimplantat zur ventralen Fusion zweier Wirbelkörper nach Anspruch 1, dadurch gekennzeichnet, daß das erste Teil (1) an der Innenseite eine keilförmige Aussparung (17) aufweist, in der ein keilförmiger Gleitblock (18) in Richtung (y) verschieblich gelagert ist, welcher auf der zu dem zweiten Teil (2) gerichteten Seite mit einer Zahnleiste (3) versehen ist, die mit der anderen Zahnleiste (4) auf der Innenseite des zweiten Teils (2) verrastbar ist und daß das elastische Polster (30) zwischen der Wand der keilförmigen Ausnehmung (17) und der Seite des Gleitblocks (18) angeordnet ist, die zum Teil (1) gerichtet ist. 25 30

7. Wirbelkörperimplantat nach Anspruch 6, dadurch gekennzeichnet, daß in horizontaler Richtung (x) weisende Führungsstifte (20, 21) vorgesehen sind, welche in zwei entsprechenden Führungskanälen (22, 23) im zweiten Teil (2) geführt sind, und daß die Führungsstifte (20, 21) zusammen mit den Führungskanälen (22, 23) die maximale Strecke der zulässigen Bewegung in horizontaler Richtung begrenzen. 35 40

8. Wirbelkörperimplantat nach Anspruch 6 oder 7, dadurch gekennzeichnet, daß die Zahnflanken (6) der Zahnleisten (3, 4) in vertikaler Richtung (y) einen Anstiegswinkel in vertikaler Richtung (y) von etwa 30° aufweisen und die Zahnflanken (7) etwa horizontal verlaufen. 45

Hierzu 2 Seite(n) Zeichnungen

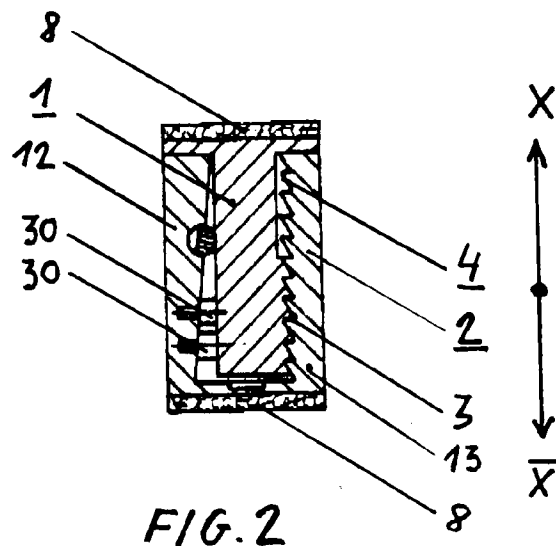
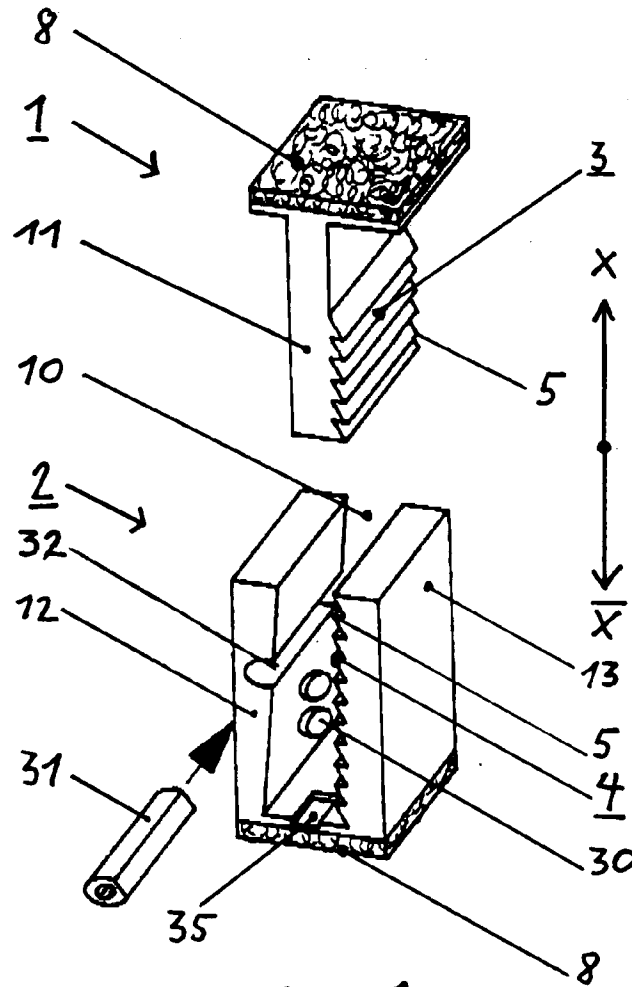
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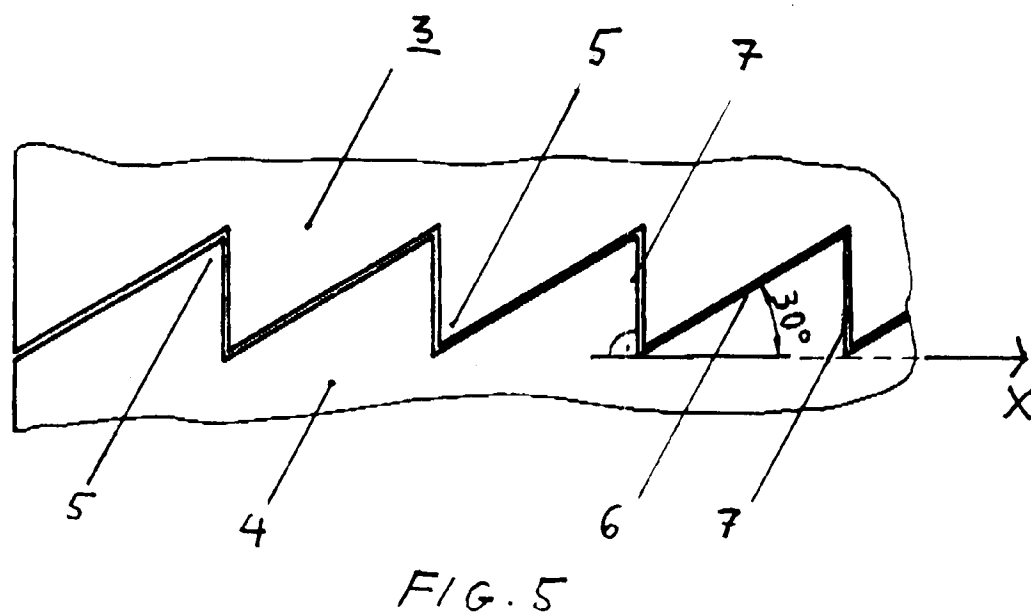
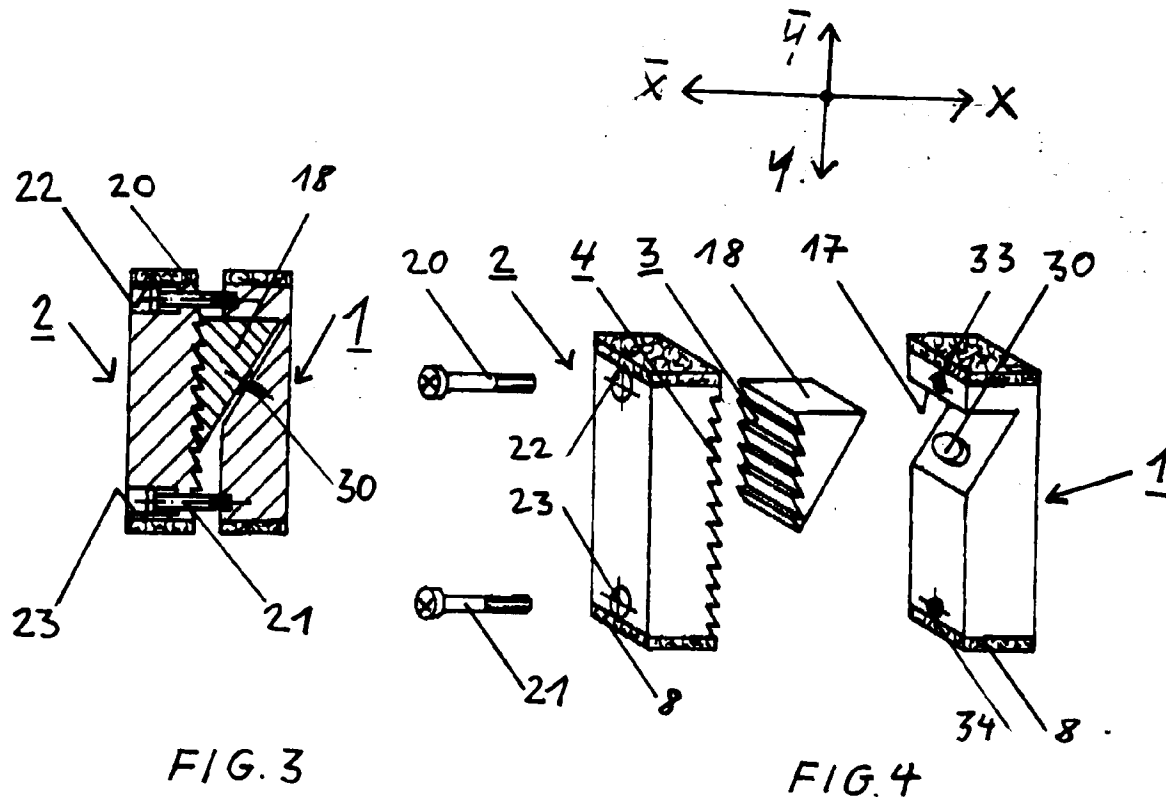
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①9 BUNDESREPUBLIK
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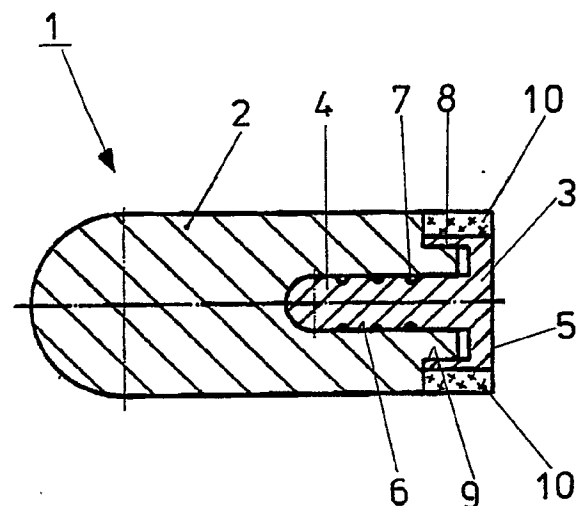
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⑤6 Für die Beurteilung der Patentfähigkeit
in Betracht gezogene Druckschriften:
DE 42 13 771 C1

⑤4 Bandscheibenteilersatz als Entlastungsteil

⑤7 Es wird ein Implantat beschrieben, welches als Entlastungsteil für eine Bandscheibe wirkt. Der erfindungsgemäße Bandscheibenteilersatz besteht aus einer distal abgerundeten Hülse (2) aus elastischem Material und einem metallischen Körper (3) mit einem Zapfen (4), der an einer Abschlußplatte (5) angebracht ist. Die Hülse (2) weist in ihrem Inneren einen Aufnahmeraum (6) für den Zapfen (4) auf. Die Abschlußplatte (5) liegt im wesentlichen an der Stirnseite der Hülse (2) an, wenn der Zapfen (4) in die Hülse gesetzt ist. Sie schließt im wesentlichen mit der Hülse bündig ab.



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Die vorliegende Erfindung betrifft einen Bandscheibenteilersatz, welcher als Entlastungsteil in lädierten Bandscheiben zum Einsatz kommt. Bei lädierten Bandscheiben besteht die Gefahr, daß zwei benachbarte Wirbel aufeinander reiben. Selbstverständlich kann es auch zu dem weit verbreiteten Bandscheibenvorfall kommen, bei dem Druck auf den Spinalkanal ausgeübt wird, infolge dessen es im schlimmsten Falle zu einer Lähmung kommen kann.

Künstliche Bandscheibenendoprothesen sind in vielfältiger Ausgestaltung bekannt. Beispielhaft sei hier jene Bandscheibendoprothese gemäß der DE 42 13 771 C1 der Anmeldering genannt. Die darin offenbarte Bandscheibendoprothese ist eine Vollendoprothese, in dem Sinne, daß die beschädigte Bandscheibe vollständig entfernt und ersetzt wird durch die Endoprothese.

Die Applikation dieser künstlichen Bandscheibe ist nicht in allen Fällen angezeigt und vonnöten. In vielen, wenn nicht gar in den meisten Fällen würde eine lokale Ausbesserung der lädierten Bandscheibe ausreichen, um negative Konsequenzen aus der Läsion zu vermeiden. Derartige, nur lokal wirkende Implantate sind zur Zeit nicht bekannt.

Es ist daher die Aufgabe der vorliegenden Erfindung, ein Implantat anzugeben, welches bei lädierten Bandscheiben zu einer spürbaren Entlastung führt.

Gelöst wird die Aufgabe durch einen Bandscheibenteilersatz gemäß dem Anspruch 1. Vorteilhafte Ausgestaltungen ergeben sich aus den Unteransprüchen.

Demgemäß wird als Implantat ein Bandscheibenteilersatz vorgeschlagen, der als Entlastungsteil wirkt. Der Bandscheibenteilersatz besteht aus einer distal abgerundeten Hülse aus elastischem Material und einem metallischen Körper mit einem Zapfen, der an einer Abschlußplatte angebracht ist. Die Hülse weist in ihrem Inneren einen Aufnahmeraum für den Zapfen auf. Wird der Zapfen in die Hülse eingeführt, so liegt schließlich die Abschlußplatte an der Stirnseite der Höhle an und schließt mit dieser im wesentlichen bündig ab. Die Hülse ist also armiert durch den metallischen Zapfen.

Der Einsatz dieses Teilersatzes kann folgendermaßen ablaufen: in der Regel werden pro Bandscheibe zwei Implantate eingesetzt. Etwa in Richtung der Querfortsätze der Wirbelkörper wird jeweils eine Bohrung in die beschädigte Bandscheibe eingebracht. Jeweils ein Bandscheibenteilersatz wird daraufhin in die Bohrung gesetzt.

Vorzugsweise besteht die Hülse aus körperverträglichem Silikon. Der metallische Teil aus Abschlußplatte und Zapfen hingegen besteht aus körperverträglichem Metall.

Zur Erhöhung der Verbundfestigkeit zwischen dem Silikon der Hülse und dem Metall des Zapfens ist dieser vorzugsweise mit einem oberflächenvergrößernden Profil versehen.

Nachfolgend wird eine besonders bevorzugte Ausführungsform des Bandscheibenteilersatzes beschrieben. Hier weist die Abschlußplatte einen umlaufenden Bund auf. Dieser Bund faßt die mit einem Absatz am proximalen Ende versehene Hülse ein. Der durchmesserermindernde Absatz der Hülse ist so ausgebildet, daß der Bund dennoch bündig mit der Hülse abschließt. Außen ist der umlaufende Bund mit einer dreidimensionalen offenmaschigen Raumnetzstruktur versehen, wie sie beispielsweise bekannt ist aus der DE 41 06 971 C1,

wobei diese Struktur im vorliegenden Falle nicht dazu dient, daß Knochentrapekel in sie hineinwachsen sollen, sondern vielmehr Bindegewebe zur Stabilisierung und Fixation des Bandscheibenteilersatzes.

Die Erfindung wird anhand der einzigen Zeichnungsfigur näher erläutert. Diese zeigt eine Ausführungsform des erfindungsgemäßen Bandscheibenteilersatzes im Schnitt.

Der Bandscheibenteilersatz 1 besteht aus einer distal abgerundeten Hülse 2. Diese weist in ihrem Inneren einen Aufnahmeraum 6 auf. Der Aufnahmeraum ist in einfacher Weise als zentrische Bohrung in der Hülse 2 ausgeführt. In den Aufnahmeraum 6 eingeführt dargestellt ist der Zapfen 4 des metallischen Teils des Implantats. Dieser ist angeformt an eine Abschlußplatte 5. Die Längenverhältnisse von Zapfen 4 und Aufnahmeraum sind so gewählt, daß die Abschlußplatte des metallischen Körpers 3 im wesentlichen an der Stirnseite der Hülse 2 anliegt.

Im abgebildeten Ausführungsbeispiel verfügt der Zapfen 4 über ein oberflächenvergrößerndes Profil 7, wodurch die Verbundfestigkeit zwischen dem Hülsenmaterial und dem metallenen Zapfen erhöht wird.

Proximal weist die Hülse 2 einen durchmessererringernden Absatz 9 auf. Dieser Absatz 9 korrespondiert in seiner Tiefe mit der Höhe des an der Abschlußplatte 5 angeformten und umlaufenden Bundes 8 mit darauf vorgesehender dreidimensionaler offenmaschiger Raumnetzstruktur 10.

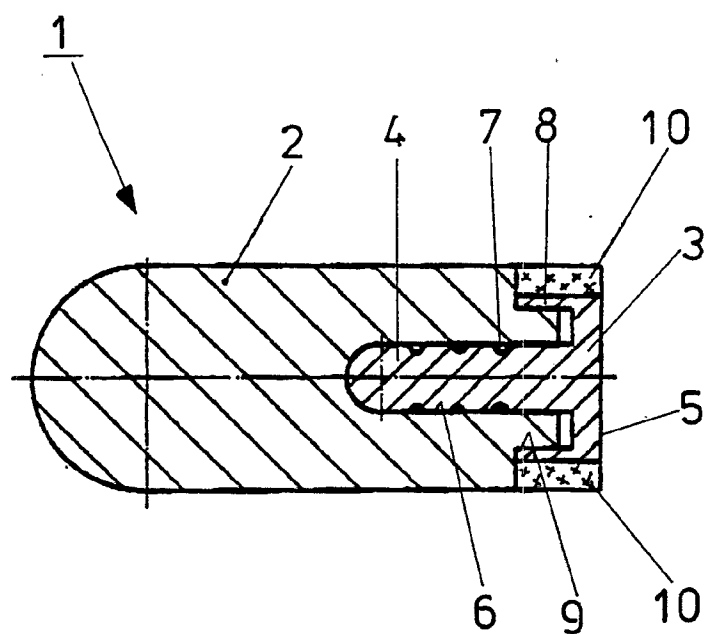
Die Raumnetzstruktur 10 ist vorliegend dafür vorgesehen, daß hier Bindegewebe einwachsen kann.

Patentansprüche

1. Bandscheibenteilersatz (1) als Entlastungsteil, bestehend aus einer distal abgerundeten Hülse (2) aus elastischem Material und einem metallischen Körper (3) mit einem Zapfen (4), der an einer Abschlußplatte (5) angebracht ist, wobei die Hülse (2) in ihrem Inneren einen Aufnahmeraum (6) für den Zapfen (4) aufweist, dergestalt, daß die Abschlußplatte (5) bei in die Hülse (2) gesetztem Zapfen (4) im wesentlichen an der Stirnseite der Hülse (2) anliegt und im wesentlichen bündig mit dieser abschließt.
2. Bandscheibenteilersatz nach Anspruch 1, bei der die Hülse (2) aus Silikon besteht.
3. Bandscheibenteilersatz nach Anspruch 1 oder 2, bei der der Zapfen (4) mit einem oberflächenvergrößernden Profil (7) versehen ist.
4. Bandscheibenteilersatz nach einem der Ansprüche 1 bis 3, bei der die Abschlußplatte (5) einen umlaufenden Bund (8) aufweist, der die mit einem Absatz (9) am proximalen Ende versehene Hülse (2) einfaßt und außen eine dreidimensionale offenmaschige Raumnetzstruktur (10) aufweist.

Hierzu 1 Seite(n) Zeichnungen

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①9 BUNDESREPUBLIK
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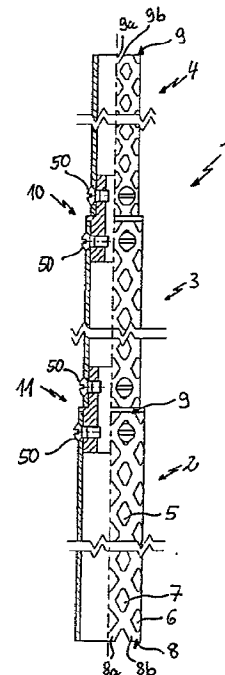
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⑤6 Für die Beurteilung der Patentfähigkeit
in Betracht gezogene Druckschriften:

EP 02 68 115 B1

⑤4 Platzhalter für Wirbel

- ⑤7 Zum Verbinden von Wirbeln mit unterschiedlicher Größe und unterschiedlichem Querschnitt wird ein Platzhalter (1) bereitgestellt, der wenigstens zwei mantelförmige Elemente (2, 3, 4) mit unterschiedlichem Querschnitt und ein Verbindungsstück (10, 11) zum Verbinden der Elemente aufweist. Der Querschnitt der Elemente (2, 3, 4) ist an den Querschnitt der miteinander zu verbindenden Wirbel angepaßt.



DE 195 00 170 C 1

Die Erfindung betrifft einen Platzhalter für Wirbel.

In einem Fall, in dem ein oder mehrere Wirbel aus der Wirbelsäule entfernt werden müssen, ist es erforderlich, einen Platzhalter zwischen die verbleibenden Teile der Wirbelsäule einzusetzen.

Aus der EP 0 268 115 B1 ist ein Platzhalter insbesondere für einen Wirbel bekannt, der ein mantelförmiges Element mit wenigstens einer Ausnehmung in der Wandung aufweist, wobei der obere und untere Rand des mantelförmigen Elements jeweils wenigstens teilweise zackenförmig ausgebildet ist. Das mantelförmige Element weist über seine gesamte axiale Länge einen gleichbleibenden Querschnitt auf.

Für den Fall, daß zwei sehr unterschiedliche Querschnitte aufweisende Wirbel der Wirbelsäule miteinander verbunden werden sollen, ist jedoch ein Platzhalter der oben beschriebenen Art ungünstig, da der Querschnitt des Platzhalters entweder zu groß für die Verbindung mit dem kleineren Wirbel oder zu klein für die Verbindung mit dem größeren Wirbel ist. Dadurch ist eine optimale kraftschlüssige Verbindung nicht gewährleistet.

Aufgabe der Erfindung ist es, einen Platzhalter für Wirbel zu schaffen, der so ausgebildet ist, daß er zur Verbindung zweier Wirbel oder zweier Knochenstücke unterschiedlicher Größe und unterschiedlichen Querschnittes oder zur platzsparenden Verbindung zweier Wirbel gleicher Größe geeignet ist.

Die Aufgabe wird gelöst durch einen Platzhalter für Wirbel nach dem Patentanspruch 1. Weiterbildungen sind in den Unteransprüchen angegeben.

Der Platzhalter für Wirbel hat den Vorteil, daß eine sehr einfache Anpassung an die Größe der zu verbindenden Wirbel und ein sehr einfacher Ersatz für Wirbel der geeigneten Größe zwischen die zu verbindenden Wirbel gegeben ist.

Weitere Einzelheiten und Zweckmäßigkeiten der Erfindung ergeben sich aus der Beschreibung von Ausführungsbeispielen anhand der Figuren.

Von den Figuren zeigen:

Fig. 1 eine teilgeschnittene Vorderansicht eines ersten Ausführungsbeispiels eines Platzhalters für Wirbel gemäß der Erfindung;

Fig. 2 eine teilgeschnittene Vorderansicht eines zweiten Ausführungsbeispiels eines Platzhalters für Wirbel gemäß der Erfindung;

Fig. 3a) bis 3c) teilgeschnittene Vorderansichten von Verbindungsstücken für Platzhalter gemäß der Erfindung.

Wie aus Fig. 1 ersichtlich ist, ist der Platzhalter 1 aus drei zylindermantelförmigen Elementen 2, 3, 4 gebildet, die über Verbindungsstücke 10, 11 miteinander verbunden sind. Der Zylindermantel eines jeden der zylindermantelförmigen Elemente 2, 3, 4 weist in der aus Fig. 1 ersichtlichen Weise rautenförmige Ausnehmungen 5 auf, die sich mit ihrer Längsdiagonalen parallel zu der Zylinderachse erstrecken. Jeweils benachbarte Reihen 6, 7 solcher rautenförmigen Ausnehmungen sind gegeneinander um eine halbe Rautenhöhe versetzt. Durch die derart netzförmig ausgebildete Wandung der zylindermantelförmigen Elemente (2, 3, 4) wird erreicht, daß eine auf die Elemente in Richtung ihrer Längsachse wirkende Belastung gleichmäßig aufgenommen wird.

Der untere Rand 8 und der obere Rand 9 jedes zylindermantelförmigen Elementes ist jeweils so ausgebildet, daß annähernd "V"-förmige Zacken 8a, 8b bzw. 9a, 9b in

der Mantelebene jeweils parallel zur Zylinderachse nach unten bzw. nach oben hervorstehen. Die Enden der Zacken 8a, 8b bzw. 9a, 9b sind so angefast bzw. angeschragt, daß sich die beiden schrägen Flächen unter einem Winkel von annähernd 45° schneiden, so daß eine Art Schneidrand gebildet ist.

Bei dem in Fig. 1 dargestellten Ausführungsbeispiel umfaßt der Platzhalter 1 drei zylindermantelförmige Elemente 2, 3, 4 der oben beschriebenen Art, wobei die Elemente jeweils gleiche Wandstärke aber unterschiedliche Mantelquerschnittsflächen aufweisen. Ein Innendurchmesser D2 des zylindermantelförmigen Elementes 3 ist kleiner als ein Innendurchmesser D3 des zylindermantelförmigen Elementes 2 und ein Innendurchmesser D1 des zylindermantelförmigen Elementes 4 ist kleiner als der Innendurchmesser D2 des zylindermantelförmigen Elementes 3. Die Elemente 2 und 3 bzw. 4 und 3 sind jeweils über Verbindungsstücke 10 bzw. 11 miteinander verbunden.

Wie aus Fig. 3a und Fig. 3b ersichtlich ist, bestehen die Verbindungsstücke 10 bzw. 11 jeweils aus einem ersten zylindermantelförmigen Abschnitt 10a bzw. 11a und einem zweiten zylindermantelförmigen Abschnitt 10b bzw. 11b. Ein Außendurchmesser D3 des Abschnittes 11a des Verbindungsstückes 11 entspricht dem Innendurchmesser des Elementes 2. Ein Außendurchmesser D2 des Abschnittes 11b des Verbindungsstückes 11 entspricht dem Innendurchmesser des Elementes 3. Ein Außendurchmesser D2 des Abschnittes 10a des Verbindungsstückes 10 entspricht dem Innendurchmesser des Elementes 3. Ein Außendurchmesser D1 des Abschnittes 10b des Verbindungsstückes 10 entspricht dem Innendurchmesser des Elementes 4.

Die ersten Abschnitte 10a bzw. 11a der Verbindungselemente 10 bzw. 11 weisen jeweils an ihrer an den zweiten Abschnitt 10b bzw. 11b angrenzenden Seite einen Vorsprung 20 bzw. 21 auf, dessen Außendurchmesser einem Außendurchmesser des Elementes 3 bzw. des Elementes 2 entspricht.

Der erste zylindermantelförmigen Abschnitt 10a bzw. 11a sowie der zweite zylindermantelförmigen Abschnitt 10b bzw. 11b der Verbindungsstücke 10 bzw. 11 weist jeweils eine Gewindebohrung 30, 40 bzw. 31, 41 zur Aufnahme einer Schraube 50 auf, deren Achse in einem rechten Winkel zur Zylinderachse verläuft. Der Durchmesser der Gewindebohrungen 30, 40, 31, 41 ist kleiner als der Abstand zweier gegenüberliegender Seiten der rautenförmigen Ausnehmung 5 der zylindermantelförmigen Elemente 2, 3 bzw. 4.

Der Abstand der Achse der Gewindebohrungen 30, 40 bzw. 31, 41 der Verbindungsstücke 10 bzw. 11 von den jeweiligen Vorsprüngen 20 bzw. 21 ist gleich dem Abstand eines Mittelpunktes einer ersten vollständigen rautenförmigen Ausnehmung 5 von dem Rand 8 bzw. 9 des zylindermantelförmigen Elementes 2, 3 bzw. 4. In zusammengesetztem Zustand sind die Elemente 2, 3, 4 des Platzhalters mit den Verbindungsstücken 10 bzw. 11 derart verschraubt, daß jeweils eine durch eine der ersten vollständigen Ausnehmungen 5 hindurchgeführte Schraube 50 in die jeweilige Gewindebohrung des Verbindungsstückes eingreift. Dabei weist ein Schraubenkopf der Schraube einen Durchmesser auf, der größer als der Abstand zweier gegenüberliegender Seiten der rautenförmigen Ausnehmung 5 ist.

Die zylindermantelförmigen Elemente 2, 3 und 4, die Verbindungsstücke 10, 11 sowie die Schrauben 50 sind aus körperverschleißfähigem Material, beispielsweise aus Titan gefertigt.

Im Betrieb werden die Querschnitte bzw. die Durchmesser der zylindermantelförmigen Elemente 2 und 4 so ausgewählt, daß sie im wesentlichen den Querschnitten bzw. den Durchmessern der miteinander zu verbindenden Wirbeln entsprechen. Der Querschnitt bzw. der Durchmesser des zylindermantelförmigen Elementes 3 wird so gewählt, daß er kleiner als der Durchmesser des zylindermantelförmigen Elementes 2 und größer als der Durchmesser des zylindermantelförmigen Elementes 4 ist. Die axialen Längen der zylindermantelförmigen Elemente 2, 3 und 4 werden so gewählt, daß in zusammen-gestecktem Zustand der Platzhalter 1 so zwischen die zu verbindenden Wirbel paßt, daß diese den ursprünglichen Abstand zueinander behalten. Anschließend werden die zylindermantelförmigen Elemente 4 bzw. 3 jeweils so über den ersten Abschnitt 10a bzw. den zweiten Abschnitt 10b des Verbindungsstückes 10 geschoben, daß die einander zugewandten Enden der Elemente 4 und 3 jeweils an dem Vorsprung 20 des Verbindungsstückes 10 anliegen. Dann wird jeweils eine der rautenförmigen Ausnehmungen 5 der Wandung der Elemente 2 bzw. 3 durch Drehen des Elementes in Deckung mit der Gewindebohrung 30 bzw. 40 des Verbindungsstückes 10 gebracht. Wie aus Fig. 1 ersichtlich ist, werden die Elemente 4 und 3 sodann jeweils über die Schrauben 50, die in die Gewindebohrungen 30 bzw. 40 eingeschraubt werden, mit dem Verbindungsstück 10 verbunden. In analoger Weise werden die Elemente 2 und 3 mit dem Verbindungsstück 11 verbunden.

Sodann greift der Platzhalter 1 mit seinen Zacken 8a, 8b des Elementes 2 bzw. mit den Zacken 9a, 9b des Elementes 4 in die Stirnseite der zu verbindenden Wirbel in der Weise ein, daß eine Torsionsbewegung des einen Wirbels gegenüber dem anderen Wirbel durch die hervorstehenden Zacken auf den jeweils anderen Wirbel übertragen bzw. gebremst wird.

Durch die Ausnehmungen hindurch wird zumindest das Innere des Platzhalters 1 mit Knochenzement ausgefüllt. Gewünschtenfalls kann so viel Knochenzement eingeführt werden, daß dieser durch die Ausnehmungen nach außen tritt und daß eine Modellierung auf der Außenfläche vorgenommen wird. Vorzugsweise wird das Ausfüllen mit Knochenzement nach dem Einsetzen des Platzhalters 1 vorgenommen. Es ist aber auch ein Ausfüllen des Innenraumes des Platzhalters 1 vor dem Einsetzen möglich.

Bei dem in Fig. 2 dargestellten Platzhalter gemäß eines zweiten Ausführungsbeispiels ist zwischen zwei zylindermantelförmigen Elementen 12, 13 mit gleichem Durchmesser ein drittes zylindermantelförmiges Element 14 mit kleinerem Durchmesser vorgesehen. Die Elemente 12, 13 und 14 weisen jeweils die im Zusammenhang mit dem ersten Ausführungsbeispiel beschriebene Struktur auf. Zum Verbinden der Elemente 12 und 14 bzw. 14 und 13 sind jeweils zwei gleichartige Verbindungsstücke 15 vorgesehen, die entsprechend den Verbindungsstücken 10 und 11 des ersten Ausführungsbeispiels ausgebildet sind. Die jeweiligen Außendurchmesser D4 bzw. D3 des ersten bzw. des zweiten zylindermantelförmigen Abschnittes 15a, 15b sind an die jeweiligen Innendurchmesser der Elemente 12 und 14 angepaßt. Der Platzhalter gemäß dieses zweiten Ausführungsbeispiels wird hauptsächlich zum Verbinden von Wirbeln mit gleichem Querschnitt verwendet, wobei bei der Verbindung jedoch Platz gespart werden muß, so daß es vorteilhaft ist, das Mittelstück, in diesem Fall das Element 14 mit geringerem Durchmesser auszubilden.

Bei den oben beschriebenen Ausführungsbeispielen

ist der Querschnitt der mantelförmigen Elemente jeweils kreisförmig ausgebildet. Bevorzugt wird jedoch der Querschnitt jeweils in Abhängigkeit von der Querschnittsform der zu verbindenden Wirbel verwendet. Für die Verbindung von Wirbeln im lumbalen Bereich weisen die mantelförmigen Elemente vorzugsweise einen nierenförmigen Querschnitt oder einen ovalen Querschnitt auf. Es besteht jedoch die Möglichkeit je nach Ausbildung der Abschnitte des Verbindungsstückes auch einen Platzhalter zu schaffen, der auf seinen beiden einander gegenüberliegenden Flächen, die jeweils mit den Wirbeln verbunden werden sollen, unterschiedliche Flächenformen vorzusehen.

Der Platzhalter muß nicht notwendigerweise aus drei mantelförmigen Elementen zusammengesetzt sein. In manchen Fällen genügen auch zwei Elemente oder es können mehr als drei Elemente erforderlich sein. Die geeignete Zusammensetzung des Platzhalters aus mehreren Elementen geeigneter Größe ermöglicht eine einfache Anpassung an die Gegebenheiten des Wirbelsatzes.

Anstelle des Ausfüllens mit Knochenzement ist es auch möglich, im Inneren des Platzhalters eigene oder Fremdknochenstücke einzusetzen, so daß der Platzhalter um das eingesetzte Knochenstück herum die Tragfunktion übernimmt. Damit wird ein sicherer Schutz des Rückenmarkkanals gegen Verschleudern des Knochenzementes oder der Knochenstücke erreicht.

Patentansprüche

1. Platzhalter für Wirbel, **gekennzeichnet durch** wenigstens zwei mantelförmige Elemente (2, 3, 4, 12, 13, 14) mit unterschiedlichem Querschnitt und wenigstens ein Verbindungsstück (10, 11, 15) zum Verbinden der Elemente.
2. Platzhalter nach Anspruch 1, dadurch gekennzeichnet, daß die Elemente (2, 3, 4, 12, 13, 14) eine zylindrische Form aufweisen.
3. Platzhalter nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß in der Wandung der mantelförmigen Elemente (2, 3, 4, 12, 13, 14) jeweils eine Ausnehmung (5) vorgesehen ist.
4. Platzhalter nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß mindestens einer der Ränder (8, 9) eines jeden mantelförmigen Elementes (2, 3, 4, 12, 13, 14) wenigstens teilweise zackenförmig mit Zacken (8a, 8b, 9a, 9b) ausgebildet ist.
5. Platzhalter nach Anspruch 3 oder 4, dadurch gekennzeichnet, daß die Wandung aus einem Blech gebildet ist, welches eine Vielzahl von annähernd viereckigen Ausnehmungen (5) aufweist, die so ausgerichtet sind, daß sich jeweils eine Diagonale der Ausnehmung im wesentlichen parallel zu einer Längsachse des Elementes (2, 3, 4, 12, 13, 14) erstreckt.
6. Platzhalter nach Anspruch 5, dadurch gekennzeichnet, daß die Ausnehmungen (5) im wesentlichen rautenförmig sind und die Diagonale die Längsdiagonale der Raute ist.
7. Platzhalter nach Anspruch 5 oder 6, dadurch gekennzeichnet, daß die Zacken (8a, 8b, 9a, 9b) jeweils durch V-förmige Ausnehmungen an den Rändern (8, 9) des Bleches gebildet sind.
8. Platzhalter nach einem der Ansprüche 4 bis 7, dadurch gekennzeichnet, daß die Zacken (8a, 8b, 9a, 9b) zum besseren Eingreifen in benachbarte Wirbelteile angefast sind.

9. Platzhalter nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß das Verbindungsstück (10, 11, 15) als mantelförmiges Element ausgebildet ist mit einem ersten Abschnitt (10a, 11a, 15a), dessen äußerer Mantelquerschnitt dem inneren Mantelquerschnitt des einen mantelförmigen Elementes (2) entspricht und mit einem zweiten Abschnitt (10b, 11b, 15b), dessen äußerer Mantelquerschnitt dem inneren Mantelquerschnitt des mit dem ersten mantelförmigen Elementes zu verbindenden zweiten mantelförmigen Elementes (3) entspricht. 5
10. Platzhalter nach Anspruch 9, dadurch gekennzeichnet, daß jeder der beiden Abschnitte (10a, 10b; 11a, 11b; 15a, 15b) eine Gewindebohrung zur Aufnahme einer Schraube (50) aufweist. 10
11. Platzhalter nach Anspruch 9 oder 10, dadurch gekennzeichnet, daß das Verbindungsstück (10, 11, 15) an der Verbindungsstelle der Abschnitte (10a, 10b; 11a, 11b) einen Vorsprung (20, 21) mit einem Querschnitt aufweist, der größer oder gleich dem größten Querschnitt der miteinander zu verbindenden Elemente (2, 3, 4, 12, 13, 14) ist. 15
12. Platzhalter nach einem der Ansprüche 9 bis 11, dadurch gekennzeichnet, daß der erste und der zweite Abschnitt (10a, 19b; 11a, 11b) des Verbindungsstückes (10, 11) zylindermantelförmig sind. 20
13. Platzhalter nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, daß das Verbindungsstück mit den mantelförmigen Elementen verschraubt ist. 25
14. Platzhalter nach einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, daß der Platzhalter drei mantelförmige Elemente (2, 3, 4; 12, 13, 14) mit zwei zur Verbindung von jeweils zwei Elementen vorgesehene Verbindungsstücken (10, 11; 15, 15) aufweist. 30
15. Platzhalter nach Anspruch 14, dadurch gekennzeichnet, daß zwei der drei mantelförmigen Elemente (12, 13) die über das dritte mantelförmige Element (14) miteinander verbunden sind, gleichen Querschnitt aufweisen. 35
16. Platzhalter nach einem der Ansprüche 1 oder 3 bis 15, dadurch gekennzeichnet, daß die Elemente und die Verbindungsstücke einen nierenförmigen Querschnitt aufweisen. 40
17. Platzhalter nach einem der Ansprüche 1 bis 16, dadurch gekennzeichnet, daß der Platzhalter aus einem körperverträglichen Material, insbesondere aus Titan, gebildet ist. 45
18. Platzhalter nach einem der Ansprüche 1 bis 17, dadurch gekennzeichnet, daß das innere der mantelförmigen Elemente mit einem Knochenzement ausgefüllt ist. 50

Hierzu 1 Seite(n) Zeichnungen

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60

65

- Leerseite -

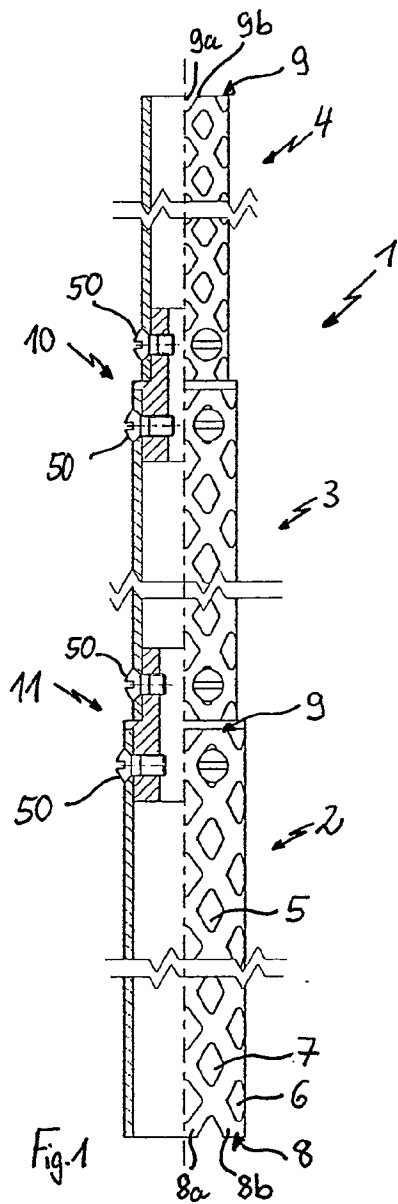


Fig. 1

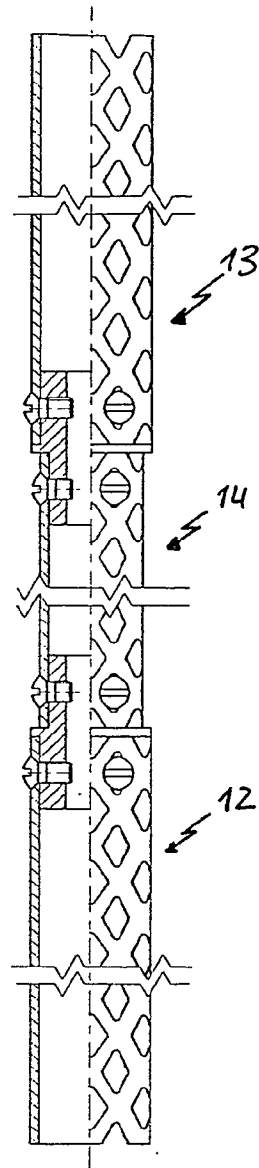


Fig. 2

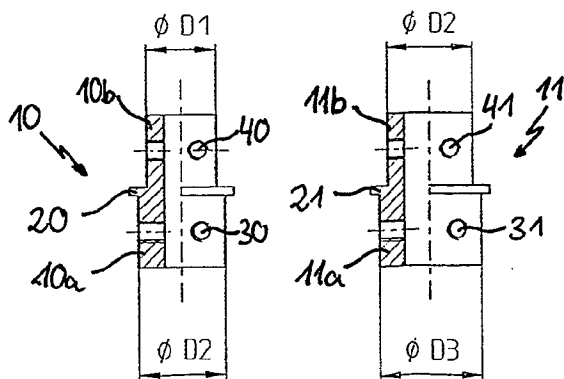


Fig. 3a

Fig. 3b

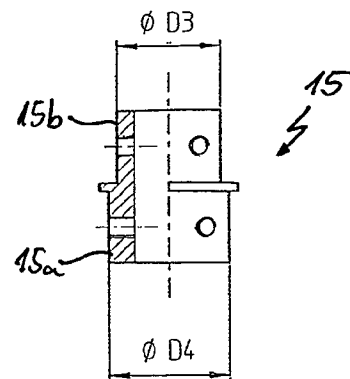


Fig. 3c



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⑤④ Distanzhaltendes Implantat zum Ersetzen von fehlenden Wirbelknochen

⑤⑦ Distanzhaltendes Implantat zum Ersetzen von fehlenden Wirbelknochen, welches aus Elementen besteht, die relativ zueinander axial bewegbar und festlegbar sind, wobei die Elemente ineinander angeordnet werden und ihre berührenden Flächen mit ineinanderpaßbaren Formgebungen versehen sind, welche ein Auseinanderziehen der Elemente ermöglichen, ihr Zusammenschieben dagegen verhindern.

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Die Erfindung betrifft ein distanzhaltendes Implantat zum Ersetzen von fehlenden Wirbelknochen, welches relativ zueinander in axialer Richtung bewegbare und festlegbare Elemente aufweist.

Es ist bekannt, daß die infolge von Verletzungen oder Entfernung von Geschwulsten entstehenden Knochenausfälle durch aus einem anderen Teil des Knochensystems entnommene körpereigene Knochen (Transplantat), Alloplastik und/oder distanzhaltende mechanische Elemente ersetzt werden können.

Auch bei der Verwendung von körpereigener oder alloplastischer Materie ist ein Abstützen der die Knochenausfallstelle umgebenden Teile erforderlich, da die Eingliederung der autologen Transplantate eine längere Zeit beansprucht und deren sofortige Belastung nicht möglich ist.

Zu diesem Zweck werden in bekannter Weise aus einem Titannetz gefertigte Zylinder verwendet, welche einerseits das zwischen die Wirbelknochen implantierte Material umgeben und gleichzeitig die benachbarten Wirbelknochen mechanisch abstützen. Derartige Zylinder aus Titannetz müssen jedoch gemeinsam mit Knochenschrauben und Fixierstäben verwendet werden, wodurch ihre Anwendung außerordentlich kompliziert und zeitaufwendig wird.

Gemäß einer anderen bekannten Lösung wird die Knochenfehlstelle durch distanzhaltende Elemente ersetzt, die eine einstellbare Länge aufweisen und mit Klauen versehen sind. Die Länge der distanzhaltenden Elemente kann mittels Schraubenbefestigung an beiden Seiten des Implantates eingestellt werden, was unter Operationsbedingungen äußerst schwierig ist.

Die Erfindung hat deshalb zum Ziel, eine Vorrichtung zum Aufrechterhalten des normalen Abstands zwischen den Wirbeln (distanzhaltendes Implantat) auszubilden, die außerordentlich einfach aufgebaut ist und auch unter Operationsbedingungen schnell, einfach und sicher implantiert werden kann.

Die gestellte Aufgabe wird durch ein distanzhaltendes Implantat zum Ersetzen von fehlenden Wirbeln gelöst, das zwei Elemente aufweist, die relativ zueinander in axialer Richtung bewegbar und festlegbar sind, wobei erfindungsgemäß die Elemente ineinander angeordnet werden können und ihre einander berührenden Flächen mit ineinander einpaßbaren Formgebungen versehen sind, die derart zusammenwirken, daß ein Auseinanderziehen der Elemente ermöglicht, ihr Zusammenschieben dagegen verhindert wird.

Bei einer bevorzugten Ausführungsform sind die Elemente Hohlkörper, wobei an der inneren Mantelfläche des äußeren Elementes im Querschnitt sägezahnförmige Nuten ausgebildet sind, und an dem dünnwandigen inneren Element im Querschnitt sägezahnförmige Rippen ausgebildet sind, die eine der Gestalt der Nuten zugeordnete bzw. sie ergänzende Form aufweisen.

Bei einer weiteren vorteilhaften Ausführungsform der Erfindung weist die innere Mantelfläche des äußeren Elementes mindestens eine axial ausgerichtete Rippe auf, wohingegen die Wand des inneren Elements mindestens einen axial ausgerichteten komplementären Schlitz aufweist, in den die Rippe eingreifen kann, so daß die beiden Elemente in ihrer Lage fixiert sind.

Bei einer anderen Ausführungsform der Erfindung ist ein Ende des äußeren Elements mit einem Boden verschlossen, dessen Außenseite mit Eingriffsklauen versehen ist, und ein Ende des inneren Elements ist ebenfalls

mit einem Boden verschlossen, dessen Außenseite mit Eingriffsklauen versehen ist. Es können jedoch auch solche Elemente verwendet werden, bei denen beide Enden offen sind, wobei an ihrem einen Ende jedoch ein mit Klauen oder einem Stützfuß versehener Pfropfen angeordnet ist.

Bei einer bevorzugten Ausführungsform der Erfindung sind die Elemente zylinderförmig und weisen einen zylindrischen Hohlraum auf, während die sägezahnförmigen Nuten als Kreisnuten und die sägezahnförmigen Rippen als umlaufende Rippen ausgebildet sind.

Weitere Merkmale und Details der Erfindung werden nachstehend anhand eines Ausführungsbeispiels in Verbindung mit den Zeichnung näher erläutert. In der Zeichnung zeigen:

Fig. 1 ein äußeres Element eines erfindungsgemäßen Implantates in Schnittdarstellung,

Fig. 2 ein inneres Element eines erfindungsgemäßen Implantates in Halbschnittdarstellung, und

Fig. 3 ein erfindungsgemäßes Implantat in Schnittdarstellung.

Das in den Figuren dargestellte äußere Element 1 und das innere Element 2 sind bei der gezeigten Ausführungsform aus den Zylindern 3 bzw. 4 ausgebildet. Die äußere Mantelfläche des äußeren Elementes 1 ist zylindrisch, in seine innere, ebenfalls zylindrische Mantelfläche sind Nuten 5 eingearbeitet. Die Nuten 5 sind im Querschnitt sägezahnförmig ausgebildet, wobei die Tiefe der Nuten jeweils in Richtung auf das Ende, in das das innere Element 2 eingeführt wird, abnimmt. Der Zylinder 3 ist unten mit einem Boden 6 abgeschlossen. Der Boden 6 ist mit Klauen 7 versehen. Auf der äußeren Mantelfläche des Zylinders 3 sind einander gegenüberliegend zwei entlang von Mantellinien verlaufende Nuten 8 ausgebildet, so daß auf der Innenseite zwei vorspringende Rippen 8a geformt sind.

Aus Fig. 2 ist ersichtlich, daß der Hohlraum des Zylinders 4 des inneren Elementes 2 ebenfalls von einem Boden 9 begrenzt ist, dessen Außenseite mit Klauen 10 versehen ist. An dem unteren Teil der äußeren Mantelfläche des Zylinders 4 sind Rippen 11 angeordnet. Diese Rippen 11 sind im Querschnitt ebenfalls sägezahnförmig und passen in die Nuten 5 des äußeren Elementes 1. Der Zylinder 4 des inneren Elementes 2 weist eine dünnere Wand auf als der Zylinder 3 des äußeren Elementes 1 und an seiner Mantelfläche sind fast über die ganze Länge Schlitz 12 ausgebildet. Die zusammen durch die dünne Wand des Zylinders 4 und die Schlitz 12 sichergestellte elastische Ausbildung ermöglicht es, wenn die Elemente einmal ineinander eingesetzt sind, daß das innere Element 2 aus dem äußeren Element 1 herausbewegbar ist, wobei die Rippen 11 des inneren Elementes 2 aus den Nuten 5 des äußeren Elementes 1 herausspringen und in die jeweils dahinterliegenden Nuten einrasten. Somit bilden das innere Element 1 und das äußere Element 2 ein längenveränderliches und -verstellbares distanzhaltendes Implantat, das gegen ein Zusammenschieben verriegelt ist, aber durch Verlagern des Elements 2 stufenweise auseinandergezogen werden kann.

Dadurch, daß die Rippen 8a des äußeren Elementes 1 und die Schlitz 12 des inneren Elementes 2 miteinander in Deckung gebracht werden, kann das Implantat in der gewünschten Lage fixiert werden, ohne daß zusätzliche Befestigungsmittel erforderlich sind.

Das Einsetzen kann im konkreten Fall so erfolgen, daß das Implantat in vollkommen zusammengeschobenem Zustand des äußeren und inneren Elementes an die Stelle der Knochenfehlstelle zwischen die nächst be-

nachbarten Wirbelknochen eingefügt wird und die Elemente mittels einer Zange so weit auseinandergezogen werden, bis die benachbarten Wirbelknochen in die gewünschte Position gelangen. Das Einsetzen besteht somit praktisch nur aus zwei einfachen Arbeitsschritten, welche auch unter Operationsbedingungen einfach und sicher durchgeführt werden können. Erforderlichenfalls können die Elemente gegeneinander in der oben erwähnten Weise unter Zusammenwirken der Rippen 8 und der Schlitz 12 verkeilt werden.

Im Vergleich mit den bekannten Implantaten vereinfacht die erfindungsgemäße Lösung in außerordentlicher Weise die Durchführung der erforderlichen Arbeitsabläufe beim Einsetzen des Implantates dadurch, daß zur Festlegung der relativ zueinander bewegbaren Elemente kein gesonderter Arbeitsschritt erforderlich ist und der einmal eingestellte Abstand sich durch eine falsche Bewegung oder aus sonstigen Gründen nicht verändern kann.

Natürlich kann das Implantat in zahlreichen Varianten ausgebildet sein, z. B. auf die Weise, daß anstelle der Klauen andere Stützelemente z. B. Stützfüße verwendet werden. Die die Elemente bildenden rohrförmigen Körper können an beiden Seiten offen sein, in diesem Fall können die Stützflächen oder Klauen pfropfenartig in das eine Ende der Elemente eingefügt werden.

Patentansprüche

1. Distanzhaltendes Implantat zum Ersetzen von fehlenden Wirbelknochen, das Elemente aufweist, die relativ zueinander axial bewegbar und festlegbar sind, **dadurch gekennzeichnet**, daß die Elemente (1, 2) ineinander angeordnet werden können und ihre einander berührenden Flächen mit miteinander in Eingriff bringbaren Formgestaltungen versehen sind, die derart zusammenwirken, daß ein Auseinanderziehen der Elemente ermöglicht, ihr Zusammenschieben dagegen verhindert wird.

2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Elemente Hohlkörper sind, wobei an der inneren Mantelfläche des äußeren Elements (1) sägezahnförmige Nuten (5) ausgebildet sind und an der äußeren Mantelfläche des inneren Elements (2) sägezahnförmige Rippen (11) ausgebildet sind, die eine an die Gestalt der Nuten (5) angepaßte bzw. diese ergänzende Form aufweisen.

3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß auf der inneren Mantelfläche des äußeren Elements (1) mindestens eine axiale Rippe (8a) ausgebildet ist und daß die Wand des inneren Elements (2) mindestens einen axialen Schlitz (12) aufweist, in den die Rippe (8a) eingreifen kann, so daß die Lage der beiden Elemente zueinander fixiert ist.

4. Implantat nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß beide Enden wenigstens eines der Elemente (1, 2) offen sind und an einem der Enden ein mit axialen Klauen (7) oder einem Stützfuß versehener Pfropfen (6) angeordnet ist.

5. Implantat nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß wenigstens ein Ende eines Elements (1, 2) mit einem Boden (9) abgeschlossen und an seiner äußeren Seite mit Klauen (7) versehen ist.

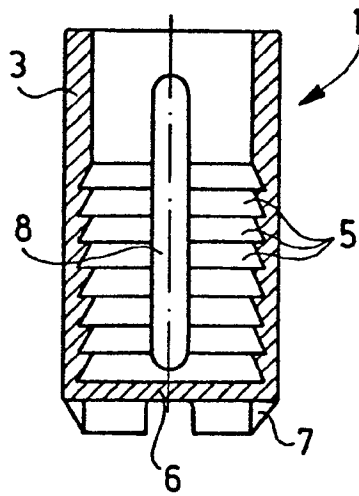


Fig. 1

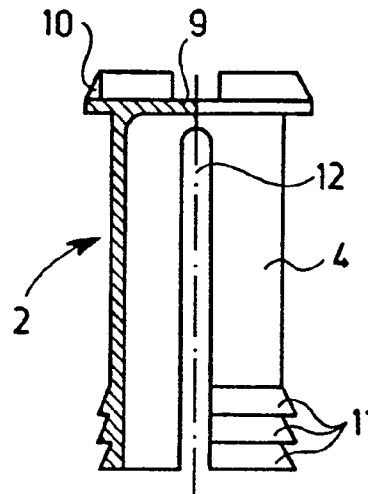


Fig. 2

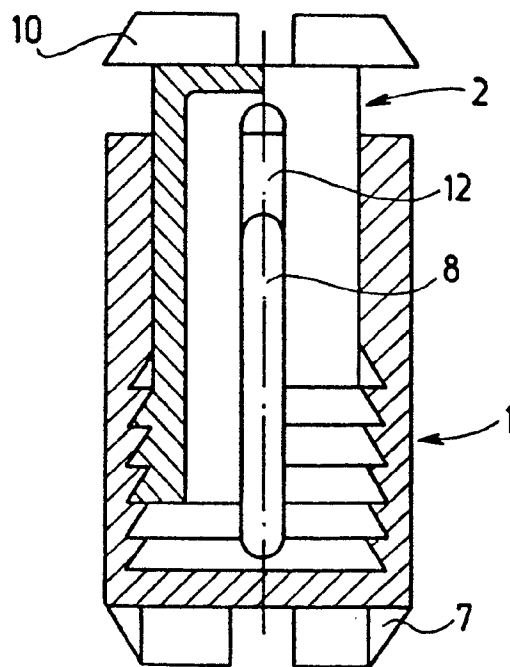


Fig. 3

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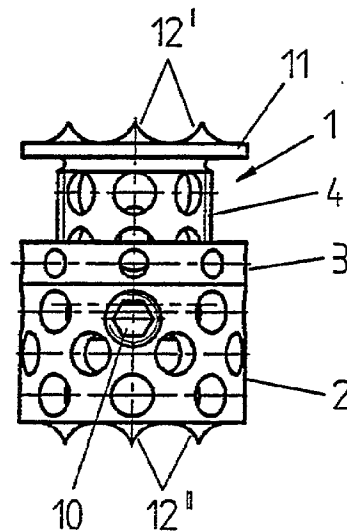
DE 196 22 827 A 1

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- ⑤4 Implantat zum Einsetzen zwischen Wirbelkörper als Platzhalter

- (57) Das Implantat besteht aus zwei endständigen, zur Anlage an den angrenzenden Wirbeln bestimmten Implantatteilen (1, 2) und einem dazwischen befindlichen mittleren Implantatteil (3), das mit einem der endständigen Implantatteile durch ein Gewinde (4) verbunden ist, wobei durch Verdrehen des mittleren Implantatteils (3) die Länge des Implantats insgesamt veränderbar ist. Die endständigen Implantatteile (1, 2) bilden rohrförmige Hülsen (5', 5'') mit von Aussparungen (6) durchbrochenen Hülsenwänden und greifen mit ihren Hülsen (5', 5'') axial ineinander, wobei sie an den Hülsenwänden axial gegeneinander verschieblich geführt sowie gegen gegenseitiges Verdrehen um die Hülsenachse gesichert sind. Das Gewinde (4) ist zwischen dem mittleren Implantatteil (3) und dem mit ihm gewindemäßig verbundenen endständigen Implantatteil (1) vorgesehen und das im Gewinde (4) verdrehbare mittlere Implantatteil (3) ist als axialer Anschlag für das andere endständige Implantatteil (2) ausgebildet.



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Die Erfindung betrifft ein Implantat zum Einsetzen zwischen Wirbelkörper als Platzhalter, bestehend aus zwei endständigen, zur Anlage an den angrenzenden Wirbeln bestimmten Implantatteilen und einem dazwischen befindlichen mittleren Implantatteil, das mit einem der endständigen Implantatteile durch ein Gewinde verbunden ist, wobei die drei Implantatteile und das Gewinde in Längsrichtung der Wirbelsäule coaxial angeordnet sind und durch Verdrehen des mittleren Implantatteils die Länge des Implantats insgesamt veränderbar ist, und wobei die endständigen Implantatteile rohrförmige Hülsen mit von Aussparungen durchbrochenen Hülsenwänden bilden.

Implantate dieser Art sind aus DE 44 23 257 A1 bekannt und dienen als Platzhalter für aus der Wirbelsäule entfernte Wirbel oder Wirbelteile. Die Implantate ermöglichen durch Verdrehen des mittleren Implantatteils eine Distraktion des das Implantat enthaltenden Wirbelsäulenbereichs. Dabei sind beide endständigen Implantatteile mit dem mittleren Implantatteil durch je ein eigenes Gewinde verbunden, wobei die beiden Gewinde in Längsrichtung der Wirbelsäule coaxial angeordnet sind und zueinander gegenläufigen Gewindesinn besitzen. Durch die Aussparungen in den Implantatteilen kann gewünschtenfalls ein in das Innere der rohrförmigen Hülsen einzubringendes Material, wie Knochenzement oder Knochenstücke, eingefügt werden, wodurch ein schnellerer Gefäßanschluß mit dem Implantat erreicht wird. Daher ist das Implantat für die Induktion der Knochenbildung und Stimulation der Knochen gut geeignet und es kann nach der Implantation leicht und schnell einwachsen. Allerdings ist bei diesen Implantaten die axiale Gesamtlänge mindestens so groß wie die Gesamtlänge der beiden gegensinnigen Gewinde, was eine Beschränkung hinsichtlich der kleinstmöglichen Implantatlänge bedeutet, so daß diese bekannten Implantate nicht als Zwischenwirbelplatzhalter zum Bandscheibenersatz geeignet sind.

Der Erfindung liegt die Aufgabe zu Grunde, ein Implantat der eingangs genannten Art so auszubilden, daß es auf eine Mindestlänge einstellbar ist, die seine Verwendung außer als kompletter Ersatz eines Wirbelkörpers, insbesondere im Halswirbelbereich, auch als Zwischenwirbelplatzhalter zum Bandscheibenersatz, insbesondere im lumbalen Bereich, ermöglicht.

Diese Aufgabe wird nach der Erfindung dadurch gelöst, daß die beiden endständigen Implantatteile mit ihren Hülsen axial ineinander greifen und an den Hülsenwänden axial gegeneinander verschieblich geführt sowie gegen gegenseitiges Verdrehen um die Hülsenachse gesichert sind, daß das Gewinde zwischen dem mittleren Implantatteil und dem mit ihm gewindemäßig verbundenen endständigen Implantatteil an dessen Hülse vorgesehen ist und daß das im Gewinde dieser Hülse verdrehbare mittlere Implantatteil als axialer Anschlag für das andere endständige Implantatteil ausgebildet ist.

Da das erfindungsgemäße Implantat nur ein einziges Gewinde besitzt, ist die mögliche Mindestlänge, auf die das Implantat verkürzt werden kann, durch die Gewindelänge nur dieses einen Gewindes bestimmt, denn die beiden endständigen Implantatteile können praktisch über die gesamte Länge ihrer rohrförmigen Hülsen völlig ineinandergeschraubt werden, was insgesamt eine axial sehr niedrige Bauform und damit die Verwendung des Implantats als Bandscheibenersatz ermöglicht. Dennoch bleibt die Distraktionsmöglichkeit des Implantats

während der Operation voll erhalten, da nur das mittlere Implantatteil im Gewinde entsprechend verdreht zu werden braucht, damit sich die Länge des Implantats insgesamt nach Wunsch ändert.

Eine im Hinblick auf die Herstellung, Montage und Handhabung besonders einfache und daher bevorzugte Ausführungsform des erfindungsgemäßen Implantats ist dadurch gekennzeichnet, daß die Hülse des mit dem mittleren Implantatteil gewindemäßig verbundenen endständigen Implantatteils das Gewinde auf seiner äußeren Umfangsfläche trägt und sowohl vom mittleren Implantatteil als auch von der Hülse des anderen endständigen Implantatteils radial außen umfaßt ist. Dadurch ist das mittlere Implantatteil zum Verdrehen leicht zugänglich und das dieses mittlere Implantatteil führende Gewinde des endständigen Implantatteils durch die Hülse des anderen endständigen Implantatteils außenseitig axial übergriffen. Auch empfiehlt es sich, die Anordnung so zu treffen, daß zur gegenseitigen Verdrehungssicherung der beiden endständigen Implantatteile in der Hülsenwand des einen Implantatteils ein axial verlaufender Führungsschlitz und an der Hülsenwand des anderen Implantatteils ein in den Führungsschlitz eingreifender Führungsvorsprung vorgesehen ist. Führungsschlitz und Führungsvorsprung können zu mehreren verteilt über den Umfang der Hülsenwände angeordnet sein. Um die gegenseitige Stellung der beiden endständigen Implantatteile auch unabhängig von der Anschlagfunktion des mittleren Implantatteils fixieren zu können, ist eine weitere vorteilhafte Ausführungsform des erfindungsgemäßen Implantats dadurch gekennzeichnet, daß die Hülse eines der endständigen Implantatteile im Überlappungsbereich der Hülsen beider endständiger Implantatteile mindestens eine radiale Gewindebohrung aufweist, in der eine gegen die Hülse des anderen endständigen Implantatteils verspannbare Klemmschraube geführt ist. In weiter bevorzugter Ausführungsform können eines oder beide der endständigen Implantatteile am jeweils vom mittleren Implantatteil abgewandten Ende mit einer ringförmigen Stirnplatte und diese Stirnplatte an ihrer Stirnfläche mit zum Eindringen in den angrenzenden Wirbel bestimmten Schneiden oder Spitzen versehen sein. Bezüglich der Ausbildung und Anordnung der Aussparungen in den Hülsenwänden der endständigen Implantatteile besteht im Rahmen der Erfindung eine gewisse Wahlfreiheit. Einerseits soll der von den Aussparungen insgesamt repräsentierte lichte Querschnitt möglichst groß sein, andererseits dürfen die Aussparungen den Gewindebereich nicht unzulässig schwächen, damit die Festigkeit der Gewindeverbindung zwischen dem einen endständigen Implantatteil und dem damit gewindemäßig verbundenen mittleren Implantatteil keine Beeinträchtigung erfährt. Im allgemeinen wird man dabei die Aussparungen als im Querschnitt kreisförmige Bohrungen oder als Langlöcher ausbilden und gleichmäßig über den Hülsenumfang verteilt anordnen. Weitere Aussparungen sind vorzugsweise in der äußeren Umfangsfläche des mittleren Implantatteils über den Umfang verteilt angeordnet und als Schlüsselöffnungen zum Einstecken eines zum Verdrehen des mittleren Implantatteiles dienenden Schlüssels ausgebildet.

Im folgenden ist die Erfindung an einem in der Zeichnung dargestellten Ausführungsbeispiel näher erläutert; es zeigen:

Fig. 1 ein Implantat nach der Erfindung in einer Seitenansicht und in dem Zustand, in dem es auf seine kleinstmöglich axiale Länge eingestellt ist,

Fig. 2 den Gegenstand der Fig. 1, jedoch im Zustand, in dem das Implantat auf seine größtmögliche Länge eingestellt ist,

Fig. 3 eine Stirnansicht des Implantats,

Fig. 4 das Implantat nach den Fig. 1 und 2 in axial auseinandergezogenem Zustand der Implantatteile,

Fig. 5 den Schnitt V-V in Fig. 4,

Fig. 6 den Schnitt VI-VI in Fig. 4,

Fig. 7 den Schnitt VII-VII in Fig. 4 und

Fig. 8 den Schnitt VIII-VIII in Fig. 4.

Das in der Zeichnung dargestellte Implantat dient zum Einsetzen zwischen in der Zeichnung selbst nicht dargestellte Wirbel als Platzhalter, und zwar, je nach Längeneinstellung des Implantats, zum Bandscheibenersatz oder für aus der Wirbelsäule entfernte Wirbel oder Wirbelteile. Das Implantat besteht aus zwei endständigen, zur Anlage an den jeweils angrenzenden Wirbeln bestimmten Implantatteilen 1, 2 und einem dazwischen befindlichen mittleren Implantatteil 3. Das mittlere Implantatteil 3 ist mit einem der beiden endständigen Implantatteile, in der Zeichnung jeweils mit dem oberen endständigen Implantatteil 1, durch ein Gewinde 4 verbunden. Die drei Implantatteile 1 bis 3 und das Gewinde 4 sind in Längsrichtung der Wirbelsäule koaxial angeordnet. Durch Verdrehen des mittleren Implantatteils 3 im Gewinde 4 ist die Länge des Implantats insgesamt zwischen den aus dem Vergleich der Fig. 1 und 2 ersichtlichen Grenzen veränderbar. Die endständigen Implantatteile 1, 2 bilden rohrförmige Hülsen 5', 5'' mit von Aussparungen 6 durchbrochenen Hülsenwänden, wobei diese Aussparungen 6 ein schnelles Einwachsen des Implantats im umgebenden Gewebe ermöglichen. Die beiden endständigen Implantatteile 1, 2 greifen mit ihren Hülsen 5', 5'' axial ineinander. Sie sind an den Hülsenwänden axial gegeneinander verschieblich geführt sowie gegen gegenseitiges Verdrehen um die Hülsenachse in noch zu erläuternder Weise gesichert. Das Gewinde 4 zwischen dem mittleren Implantatteil 3 und dem mit ihm gewindemäßig verbundenen endständigen, in der Zeichnung also oberen Implantatteil 1 ist an dessen Hülse 5' vorgesehen. Das im Gewinde 4 dieser Hülse 5' verdrehbare mittlere Implantatteil 3 ist als axialer Anschlag für die Hülse 5'' des anderen, in der Zeichnung unteren endständigen Implantatteils 2 ausgebildet. Durch Verdrehen des mittleren Implantatteils 3 im Gewinde 4 des oberen endständigen Implantatteils 1 ändert sich die axiale Lage des mittleren Implantatteils 3 auf dem oberen endständigen Implantatteil 1, so daß sich auch die axiale Lage der beiden endständigen Implantatteile 1 zueinander ändert, da die Lage des in der Zeichnung unteren endständigen Implantatteils 2 gegenüber dem in der Zeichnung oberen endständigen Implantatteil 1 durch den Anschlag seiner Hülse 5'' am mittleren Implantatteil 3 bestimmt ist. Die Hülse des mit dem mittleren Implantatteil 3 gewindemäßig verbundenen, also oberen endständigen Implantatteils 1 trägt das Gewinde 4 auf ihrer äußeren Umfangsfläche. In dieses Gewinde 4 greift das die Hülse 5' radial an ihrer Außenseite umgebende mittlere Implantatteil 3 mit einem Muttergewinde 4'. Die Hülse 5' des mit dem mittleren Implantatteil 3 gewindemäßig verbundenen endständigen, also in der Zeichnung oberen Implantatteils 1 ist außer vom mittleren Implantatteil 3 auch von der Hülse 5'' des anderen endständigen Implantatteils 2 radial außen umfaßt. Zur gegenseitigen Verdrehungssicherung der beiden endständigen Implantatteile 1, 2 ist in der Hülsenwand des in der Zeichnung oberen endständigen Implantatteils 1 ein axial verlaufender Führungsschlitz 7 und an der Hül-

senwand des anderen, in der Zeichnung unteren Implantatteils 2 ein in den Führungsschlitz 7 eingreifender Führungsvorsprung 8 vorgesehen. Der Führungsvorsprung 8 ist durch einen radial in die Hülsenwand eingesetzten Stift 8' gebildet. Der Führungsschlitz 7 bestimmt mit seiner Länge das Maß, um welches die beiden endständigen Implantatteile 1, 2 gegeneinander axial verschoben werden können. Weiter besitzt die Hülse 5'' des unteren endständigen Implantatteils 2 im Überlappungsbereich mit der Hülse 5' des oberen endständigen Implantatteils 1 mindestens eine radiale Gewindebohrung 9, in der eine nur in Fig. 1 und 2 dargestellte, gegen die Hülse 5' des oberen endständigen Implantatteils 1 verspannbare Klemmschraube 10 geführt ist, so daß bei angezogener Klemmschraube 10 die beiden endständigen Implantatteile 1, 2 axial nicht auseinandergezogen werden können. Weiter ist das obere endständige Implantatteil 1 am vom mittleren Implantatteil 3 abgewandten Ende mit einer über den Gewindedurchmesser radial nach außen vorstehenden ringförmigen Stirnplatte 11 versehen, an deren Stirnfläche zum Eindringen in den angrenzenden Wirbel bestimmte Schneiden oder Spitzen 12' vorgesehen sind. Entsprechende Schneiden bzw. Spitzen 12'' befinden sich am axial gegenüberliegenden stirnseitigen Hülsenrand des unteren endständigen Implantatteils 2. Das mittlere Implantatteil 3 ist an seiner äußeren Umfangsfläche mit über den Umfang verteilt angeordneten Aussparungen 13 versehen, die als Schlüsselöffnungen zum Einstecken eines zum Verdrehen des mittleren Implantatteils 3 dienenden, selbst nicht dargestellten Schlüssels ausgebildet sind.

Patentansprüche

1. Implantat zum Einsetzen zwischen Wirbelkörper als Platzhalter, bestehend aus zwei endständigen, zur Anlage an den angrenzenden Wirbeln bestimmten Implantatteilen (1, 2) und einem dazwischen befindlichen mittleren Implantatteil (3), das mit einem der endständigen Implantatteile durch ein Gewinde (4) verbunden ist, wobei die drei Implantatteile (1, 2, 3) und das Gewinde (4) in Längsrichtung der Wirbelsäule koaxial angeordnet sind und durch Verdrehen des mittleren Implantatteils (3) die Länge des Implantats insgesamt veränderbar ist, und wobei die endständigen Implantatteile (1, 2) rohrförmige Hülsen (5', 5'') mit von Aussparungen (6) durchbrochenen Hülsenwänden bilden, **dadurch gekennzeichnet**, daß die beiden endständigen Implantatteile (1, 2) mit ihren Hülsen (5', 5'') axial ineinander greifen und an den Hülsenwänden axial gegeneinander verschieblich geführt sowie gegen gegenseitiges Verdrehen um die Hülsenachse gesichert sind, daß das Gewinde (4) zwischen dem mittleren Implantatteil (3) und dem mit ihm gewindemäßig verbundenen endständigen Implantatteil (1) an dessen Hülse (5') vorgesehen ist und daß das im Gewinde (4) dieser Hülse (5') verdrehbare mittlere Implantatteil (3) als axialer Anschlag für das andere endständige Implantatteil (2) ausgebildet ist.

2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Hülse (5') des mit dem mittleren Implantatteil (3) gewindemäßig verbundenen endständigen Implantatteils (1) das Gewinde (4) auf seiner äußeren Umfangsfläche trägt und sowohl vom mittleren Implantatteil (3) als auch von der Hülse (5'') des anderen endständigen Implantatteils

(2) radial außen umfaßt ist.

3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß zur gegenseitigen Verdrehungssicherung der beiden endständigen Implantatteile (1, 2) in der Hülse wand des einen Implantatteils (1) ein axial verlaufender Führungsschlitz (7) und an der Hülse wand des anderen Implantatteils (2) ein in den Führungsschlitz (7) eingreifender Führungsvorsprung (8) vorgesehen ist.

4. Implantat nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die Hülse (5'') eines der endständigen Implantatteile (1, 2) im Überlappungsbereich der Hülsen (5', 5'') beider endständiger Implantatteile (1, 2) mindestens eine radiale Gewindebohrung (9) aufweist, in der eine gegen die Hülse (5') des anderen endständigen Implantatteils (1) verspannbare Klemmschraube (10) geführt ist.

5. Implantat nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß eines der beiden endständigen Implantatteile (1, 2) am vom mittleren Implantatteil (3) abgewandten Ende mit einer ringförmigen Stirnplatte (11) und diese Stirnplatte (11) an ihrer Stirnfläche mit zum Eindringen in den angrenzenden Wirbel bestimmten Schneiden oder Spitzen (12', 12'') versehen ist.

6. Implantat nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß das mittlere Implantatteil (3) an seiner äußeren Umfangsfläche über den Umfang verteilt angeordnete Ausparungen (13) aufweist, die als Schlüsselöffnungen zum Einstecken eines zum Verdrehen des mittleren Implantatteils (3) dienenden Schlüssels ausgebildet sind.

Hierzu 8 Seite(n) Zeichnungen

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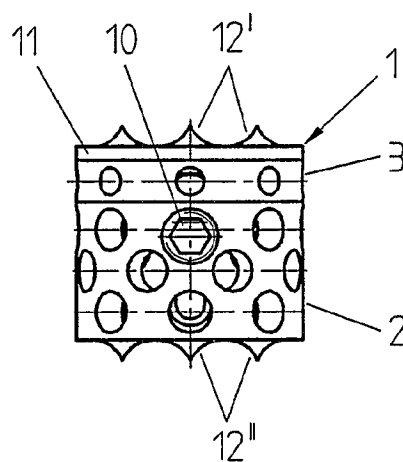


Fig. 1

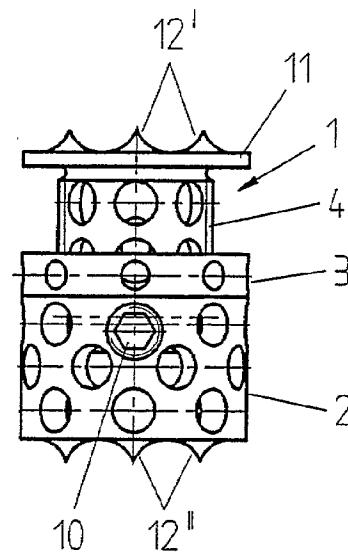


Fig. 2

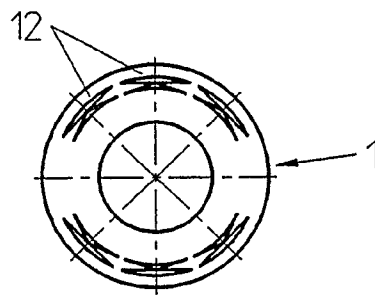


Fig. 3

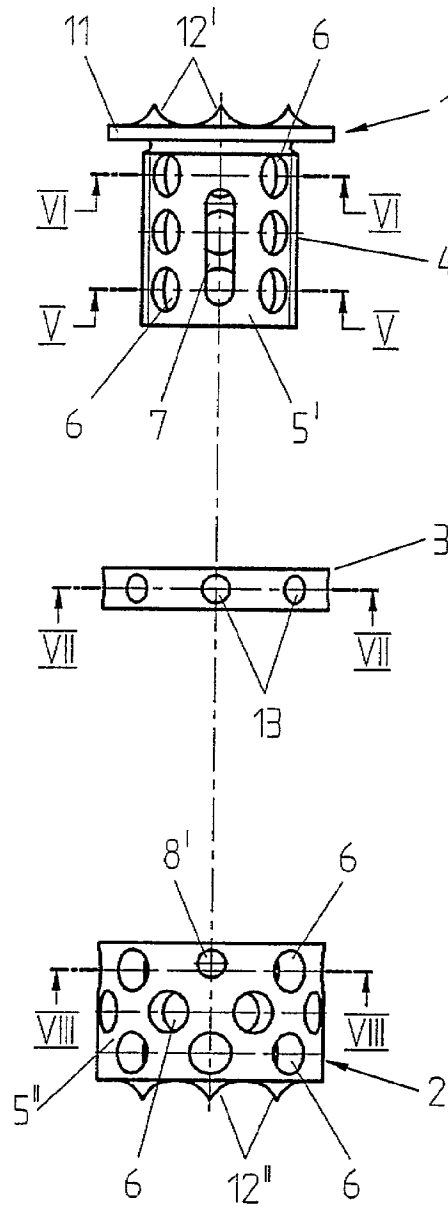


Fig. 4

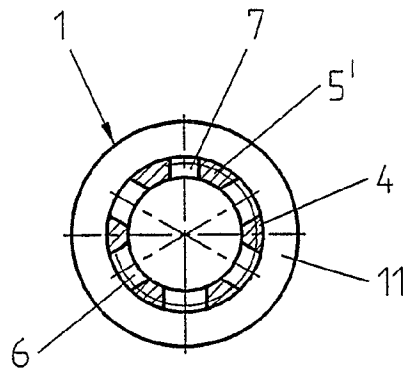


Fig. 5

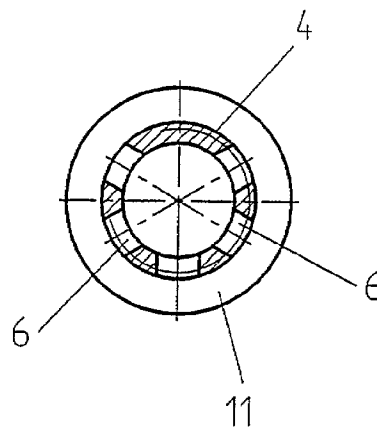


Fig. 6

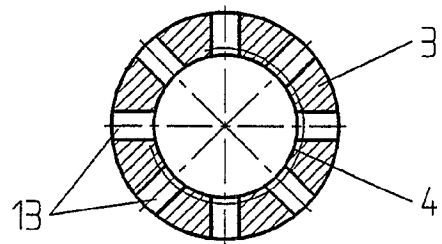


Fig. 7

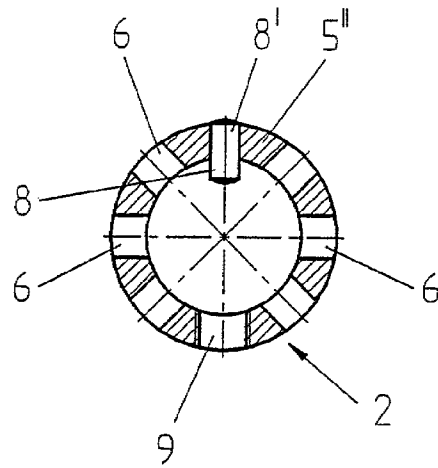


Fig. 8

(12)

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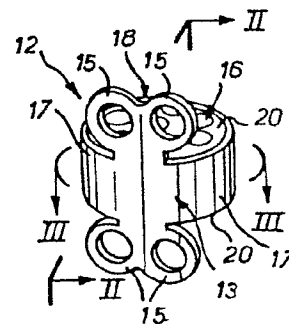
(54) **Prothèse vertébrale, en particulier pour vertèbres cervicales.**

(57) Il s'agit d'une prothèse vertébrale du genre comportant une plaquette (13) propre à être rapportée, par exemple par des vis, sur deux vertèbres distinctes.

Suivant l'invention, cette plaquette (13) porte transversalement, par avance, dans sa zone médiane, un greffon artificiel (16).

Application, notamment, aux vertèbres cervicales.

FIG. 1



Prothèse vertébrale, en particulier pour vertèbres
cervicales.

La présente invention concerne d'une manière générale les prothèses vertébrales, et elle vise plus particulièrement, mais non exclusivement, celles susceptibles d'être appliquées aux vertèbres cervicales.

5 Ainsi qu'on le sait, par suite d'une dégénérescence naturelle due au vieillissement, ou d'un traumatisme résultant par exemple d'une pratique sportive ou d'un accident, les vertèbres cervicales peuvent être le siège d'une situation pathologique conduisant un ou plusieurs des disques vertébraux qui
10 les séparent deux à deux à presser, plus ou moins fermement, à l'arrière, dans le canal médullaire, la moelle épinière et le réseau sensitif correspondant.

Il y a dès lors ce qu'il est convenu d'appeler une "hernie discale" ou bien un "ostéophyte", qu'il faut traiter.

15 Pour ce faire, le praticien doit intervenir par l'avant, l'accès par l'arrière se trouvant occulté par la moelle épinière.

Autrement dit, pour avoir accès à la lésion discale à traiter, le praticien doit passer à travers le disque vertébral concerné, et donc l'éliminer.
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Dans la plupart des cas, et c'est le cas pour les vertèbres cervicales, il faut remplacer par un greffon le disque vertébral ainsi éliminé.

La retenue élastique développée par les vertèbres qu'il
25 faut écarter pour sa mise en place suffit parfois au maintien naturel d'un tel greffon, avant la réossification de l'ensemble.

Mais, le plus souvent, notamment lorsque deux niveaux distincts sont à traiter, c'est-à-dire lorsque l'intervention
30 concerne non pas un seul disque vertébral mais deux, ou lorsque cette intervention est due à un traumatisme relativement important, il faut procéder à la mise en place d'une prothèse pour le maintien de ce greffon.

Il s'agit, en pratique, à ce jour, d'une simple plaquette,
35 te, en acier par exemple, propre à être rapportée, par l'avant, sur deux vertèbres distinctes, par exemple par des vis.

L'expérience montre qu'une telle plaquette est par elle-

même bien tolérée, et qu'il n'est que très rarement nécessaire de la retirer par la suite.

A ce jour, le greffon mis en oeuvre est un greffon naturel, et il est usuellement prélevé sur la tranche de l'os iliaque du patient à traiter.

Par sa zone périphérique, corticale, et donc dure, qui est en forme de fer à cheval, un tel greffon présente la dureté et la résistance mécanique nécessaire, tandis que, par sa zone centrale, qui est spongieuse, il est avantageusement très facilement réhabitable par un bourgeonnement osseux, les plateaux vertébraux qui l'encadrent ayant été par ailleurs légèrement avivés lors de l'intervention pour stimuler la formation de cellules osseuses et ainsi favoriser l'ostéogenèse recherchée pour la prise de l'ensemble.

Cependant, la mise en oeuvre, ainsi, d'un greffon naturel, conduit à des inconvénients, sinon majeurs, au moins non négligeables.

Tout d'abord, son prélèvement sur le patient impose une intervention supplémentaire à celui-ci, et l'expérience montre que, en raison notamment de la masse musculaire inévitablement concernée par cette dernière, le temps global de récupération pour le patient se trouve fréquemment singulièrement alourdi.

En outre, la prise d'un tel greffon naturel est toujours relativement longue, et elle peut imposer au patient le port d'un plâtre ou d'une minerve pendant de nombreuses semaines.

Enfin, cette prise, qui n'est jamais acquise, peut être déficiente.

La présente invention a d'une manière générale pour objet une prothèse vertébrale susceptible de minimiser, sinon annuler, ces inconvénients.

D'une manière plus précise, elle a pour objet une prothèse vertébrale du genre comportant une plaquette propre à être rapportée, par exemple par des vis, sur deux vertèbres distinctes, cette prothèse vertébrale étant caractérisée d'une manière générale en ce que, dans sa zone médiane, la dite plaquette porte transversalement par avance un greffon artificiel.

Ainsi, cette prothèse vertébrale, qui convient aussi bien au cas où un seul niveau est à traiter qu'au cas où deux niveaux distincts nécessitent une intervention, sa hauteur, et celle du greffon artificiel qu'elle comporte, étant alors
5 prévues en conséquence, conserve les avantages dus à la présence d'une plaquette de maintien, tout en éliminant les inconvénients usuellement attachés, tel que rappelé ci-dessus, à la mise en oeuvre d'un greffon naturel.

Il s'avère en effet que, indépendamment du fait que toute intervention spécifique de prélèvement est évitée, un tel greffon artificiel est avantageusement susceptible de conduire à une réduction notable du temps de port éventuel d'un plâtre ou d'une minerve, aucun inconvénient majeur n'étant par exemple à craindre en cas de prise plus ou moins différée.

15 La récupération d'ensemble du patient est donc avantageusement plus réduite et plus sûre.

Les caractéristiques et avantages de l'invention ressortiront d'ailleurs de la description qui va suivre, à titre d'exemple, en référence aux dessins schématiques annexés sur
20 lesquels :

la figure 1 est une vue en perspective d'une prothèse vertébrale suivant l'invention ;

la figure 2 en est une vue en coupe axiale, suivant la ligne II-II de la figure 1 ;

25 la figure 3 en est une vue en coupe transversale, suivant la ligne III-III de la figure 1 ;

la figure 4 est une vue qui, analogue à celle de la figure 2, illustre, à échelle inférieure, la mise en place de la prothèse suivant l'invention entre deux vertèbres cervicales ;
30

les figures 5 et 6 sont des vues en coupe transversale, qui, analogues à celle de la figure 3, concernent chacune respectivement une variante de réalisation.

Ces figures illustrent, à titre d'exemple, en trait
35 plein, le cas où seul un niveau est à traiter, entre les plateaux vertébraux 10 de deux vertèbres 11 successives, tel que schématisé en traits fins sur la figure 4.

La prothèse vertébrale 12 mise en oeuvre à cet effet

suivant l'invention comporte, de manière connue en soi, une plaquette 13 propre à être rapportée, par exemple par des vis 14, tel que représenté, sur les deux vertèbres 11 concernées, et, plus précisément, sur la face avant de leurs plateaux vertébraux 10.

Dans la forme de réalisation représentée, la plaquette 13 présente à cet effet, à chacune de ses extrémités, deux oreilles 15, propres chacune au passage d'une telle vis 14.

Ces oreilles 15, qui sont jumelées, sont globalement cintrées, à l'image de la face avant du plateau vertébral 10 d'une vertèbre 11.

Suivant l'invention, la plaquette 13 porte transversalement, par avance, un greffon artificiel 16.

En pratique, et tel que représenté, ce greffon artificiel 16 est au moins partiellement enserré, sur une partie au moins de son périmètre, par deux bras 17 solidaires de la plaquette 13 qui le porte.

Dans la forme de réalisation plus particulièrement représentée sur les figures 1 à 4, ces bras 17 se rejoignent l'un l'autre, et forment ainsi conjointement une enveloppe 18 qui enserre le greffon artificiel 16 sur la totalité de son périmètre.

Plus précisément, dans cette forme de réalisation, cette enveloppe 18 est tubulaire, elle a en section un contour circulaire, et elle est d'un seul tenant avec la plaquette 13, l'ensemble des bras 17 qu'elle forme et du greffon artificiel 16 qu'elle enserre s'étendant conjointement en porte-à-faux à compter de la zone médiane de ladite plaquette 13, entre les oreilles 15 de celle-ci, à la manière d'une console.

En pratique, la plaquette 13 et l'enveloppe 18 sont en métal, et par exemple en acier inoxydable ou en titane.

L'ensemble peut par exemple être obtenu par découpe appropriée d'un tronçon de tube d'un tel métal ou alliage, ou être obtenu par découpe et pliage appropriés d'un flan initialement plat de celui-ci, les bras 17 ayant alors leurs extrémités, convenablement affrontées l'une à l'autre par cintrage, éventuellement solidarisées l'une à l'autre, par exemple par soudage.

Mais il va de soi que tout autre mode de fabrication peut convenir.

Le greffon artificiel 16, quant à lui, est de préférence en céramique, et par exemple en alumine frittée.

5 Il s'avère, en effet, que, en milieu osseux, une telle matière, qui est par ailleurs bien tolérée, présente par elle-même une certaine agressivité de nature à en favoriser l'enrochement.

10 En pratique, le greffon artificiel 16 se présente, dans la forme de réalisation représentée, sous la forme d'un tronçon de cylindre, qui affleure à la surface de l'enveloppe 18 qui l'enserme, et dont les surfaces transversales correspondantes 20 sont, à l'image de celles de celle-ci, globalement planes, perpendiculairement à la direction d'allongement de
15 la plaquette 13.

De préférence, le greffon artificiel 16 présente, en creux, sur chacune de ses surfaces transversales 20, des logements 21 propres à favoriser un bourgeonnement osseux.

20 En pratique, et tel que représenté, ces logements 21 s'étendent en tubes de l'une à l'autre des surfaces transversales 20 du greffon artificiel 16.

Ils constituent ainsi avantageusement, lorsqu'ils sont envahis par le bourgeonnement osseux résultant de l'ostéogénèse recherchée, un guide favorable à une prolifération en
25 ligne de ce bourgeonnement osseux.

De préférence, le greffon artificiel 16 ainsi constitué est brut d'usinage.

Il présente donc, tant sur ses surfaces transversales 20 qu'à l'intérieur de ses logements 21, un grain de surface non
30 négligeable, compris entre 1 à 50 microns par exemple, favorable à un bon accrochage mécanique du bourgeonnement osseux qui doit l'envahir.

En pratique, ce greffon artificiel 16 est simplement engagé à force dans l'enveloppe 18 qui l'enserme.

35 Pour faciliter un tel engagement, l'ensemble que constitue cette enveloppe 18 et la plaquette 13 qui la porte peut être préalablement chauffé, et il en résulte, au refroidissement, au moins dans une certaine mesure, un frettage plus ou

moins prononcé du greffon artificiel 16, favorable à la tenue de celui-ci.

Mais un tel frettage n'est pas impératif.

En outre, lorsque seuls de simples bras 17 distincts sont
5 mis en oeuvre, ces bras 17 sont simplement refermés, sans nécessairement se rejoindre, sur le greffon artificiel 16 qu'ils doivent enserrer.

La mise en place de la prothèse vertébrale 12 suivant l'invention se fait suivant un processus usuel.

10 Après avoir préparé l'implantation des vis 14 sur les vertèbres 11 concernées, et avoir avivé les faces concernées de leur plateau vertébral 10, tel que schématisé en traits interrompus à la figure 4, en correspondance avec la hauteur H du greffon artificiel 16, la prothèse vertébrale 12 suivant
15 l'invention est engagée, par ce greffon artificiel 16, entre les plateaux vertébraux 10 ainsi avivés, jusqu'à contact de sa plaquette 13 contre la face avant de ceux-ci, et les vis 14 sont alors à leur tour mises en place.

Dans ce qui précède, il a été supposé que, comme indiqué,
20 seul un niveau est à traiter.

Mais, tel que schématisé en traits interrompus à la figure 4, dans le cas où deux niveaux nécessitent simultanément une intervention, soit parce que deux disques adjacents sont atteints par un processus pathologique, soit parce que tout
25 le plateau ou corps vertébral compris ces deux disques doit être remplacé, comme cela se voit dans les destructions cancéreuses ou dans les fractures graves, la hauteur H du greffon artificiel 16 est choisie en conséquence, et donc celle de l'ensemble de la prothèse vertébrale 12 mise en oeuvre,
30 avec élimination du plateau vertébral 10 intermédiaire.

Dans la variante de réalisation représentée sur la figure 5, le greffon artificiel 16 conserve extérieurement un contour circulaire, mais les bras 17 n'ayant pas une épaisseur constante, il se trouve excentré par rapport au contour
35 extérieur de ces bras 17.

En outre, et tel que représenté en trait plein sur cette figure 5, les bras 17 peuvent ne pas se rejoindre l'un l'autre, une fente 22 subsistant alors entre eux en service.

Mais, tel que schématisé en traits interrompus, ils peuvent aussi bien se rejoindre l'un l'autre, comme précédemment.

Dans la variante de réalisation illustrée par la figure 6, une forme en fer à cheval, ou en U, analogue à celle d'un greffon artificiel, est conservée.

Tel que représenté en trait plein, les bras 17 peuvent être distincts, et n'enserrer ainsi le greffon artificiel 16 que sur trois côtés.

Mais, comme précédemment, et tel que schématisé en traits interrompus, ce greffon artificiel 16 peut aussi être enserré sur la totalité de son périmètre.

La présente invention ne se limite d'ailleurs pas aux formes de réalisation décrites et représentées, mais englobe toute variante d'exécution et/ou de combinaison de leurs divers éléments.

En particulier, les bras enserrant le greffon artificiel mis en oeuvre ne sont pas nécessairement d'un seul avec la plaquette qui les porte.

Ils peuvent aussi bien être rapportés de toute manière appropriée sur cette plaquette, par exemple par soudage.

De plus, au lieu d'être elles aussi d'un seul tenant avec cette plaquette, les oreilles que présente celle-ci pour le passage d'un moyen de fixation peuvent être montées ajustables en position sur une telle plaquette.

L'ouverture que présentent de telles oreilles pour le passage d'un tel moyen de fixation peut en outre, au lieu d'être circulaire, comme plus particulièrement représenté, être allongée en boutonnière, pour permettre également, au moins dans une certaine mesure, un ajustement en position de l'ensemble.

Corollairement, les logements que présente en creux le greffon artificiel mis en oeuvre ne forment pas nécessairement des tubes d'une des surfaces transversales à l'autre de celui-ci, bien que cette disposition soit préférée, et/ou les dites surfaces transversales ne sont pas nécessairement planes.

Pour le traitement d'un même niveau, deux demi-greffons peuvent d'ailleurs être mis en oeuvre, dos à dos, en étant

par exemple enchâssés dans une même console, l'un pour contact avec le plateau vertébral supérieur du niveau concerné, l'autre pour contact avec le plateau inférieur de ce même niveau.

5 Dans le cas où des dispositions propres à un ajustement en position sont adoptées, deux greffons distincts, convenablement étagés de manière réglable, peuvent être mis en oeuvre, pour le traitement de deux niveaux différents.

10 Enfin, le domaine d'application de l'invention ne se limite pas à celui des seules vertèbres cervicales mais s'étend au contraire également aussi bien à celui des vertèbres dorsales ou lombaires.

REVENDICATIONS

1. Prothèse vertébrale du genre comportant une plaquette (13) propre à être rapportée, par exemple par des vis, sur deux vertèbres distinctes, caractérisée en ce que, dans sa zone médiane, ladite plaquette (13) porte transversalement par avance un greffon artificiel (16).

2. Prothèse vertébrale suivant la revendication 1, caractérisée en ce que le greffon artificiel (16) est au moins partiellement enserré, sur une partie au moins de son périmètre, par deux bras (17) solidaires de la plaquette (13) qui le porte.

3. Prothèse vertébrale suivant la revendication 2, caractérisée en ce que, se rejoignant l'un l'autre, lesdits bras (17) forment conjointement une enveloppe (18) qui enserre le greffon artificiel (16) sur la totalité de son périmètre.

4. Prothèse vertébrale suivant la revendication 3, caractérisée en ce que ladite enveloppe (18) est tubulaire.

5. Prothèse vertébrale suivant la revendication 4, caractérisée en ce que ladite enveloppe (18) a en section un contour circulaire.

6. Prothèse vertébrale suivant l'une quelconque des revendications 2 à 5, caractérisée en ce que le greffon artificiel (16) et les bras (17) qui l'enserrent s'étendent conjointement en porte-à-faux à compter de la plaquette (13) qui les porte, à la manière d'une console.

7. Prothèse vertébrale suivant l'une quelconque des revendications 2 à 6, caractérisée en ce que les bras (17) qui enserrant le greffon artificiel (16) sont d'un seul tenant avec la plaquette (13) dont ils sont solidaires.

8. Prothèse vertébrale suivant l'une quelconque des revendications 1 à 7, caractérisée en ce que, la plaquette (13) présentant à ses extrémités des oreilles (15) propres au passage de moyens de fixation tels que des vis, le greffon artificiel (16) s'étend entre lesdites oreilles (15).

9. Prothèse vertébrale suivant l'une quelconque des revendications 1 à 8, caractérisée en ce que le greffon artificiel (16) présente en creux à sa surface des logements (21) propres à favoriser un bourgeonnement osseux.

10. Prothèse vertébrale suivant la revendication 9, caractérisée en ce que lesdits logements (21) s'étendent en tubes de l'une à l'autre des surfaces transversales (20) du greffon artificiel (16).

- 5 11. Prothèse vertébrale suivant l'une quelconque des revendications 1 à 10, caractérisée en ce que, alors que la plaque (13) qui le porte est en métal, le greffon artificiel (16) est en alumine frittée.

FIG. 1

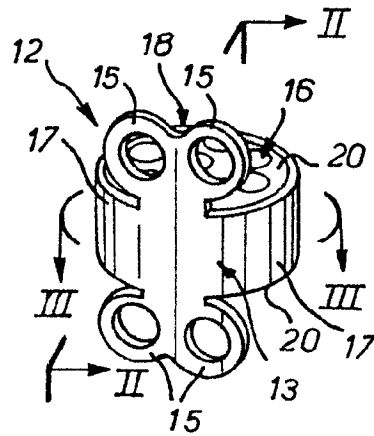


FIG. 2

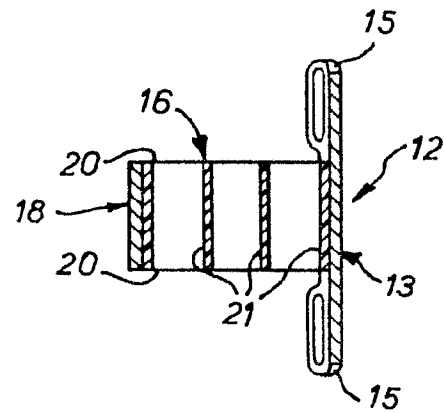


FIG. 3

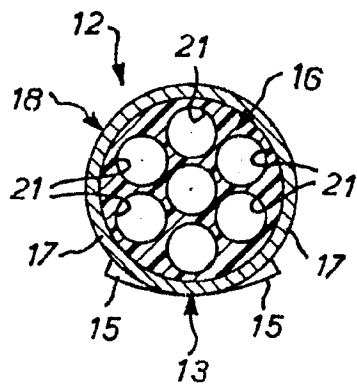


FIG. 4

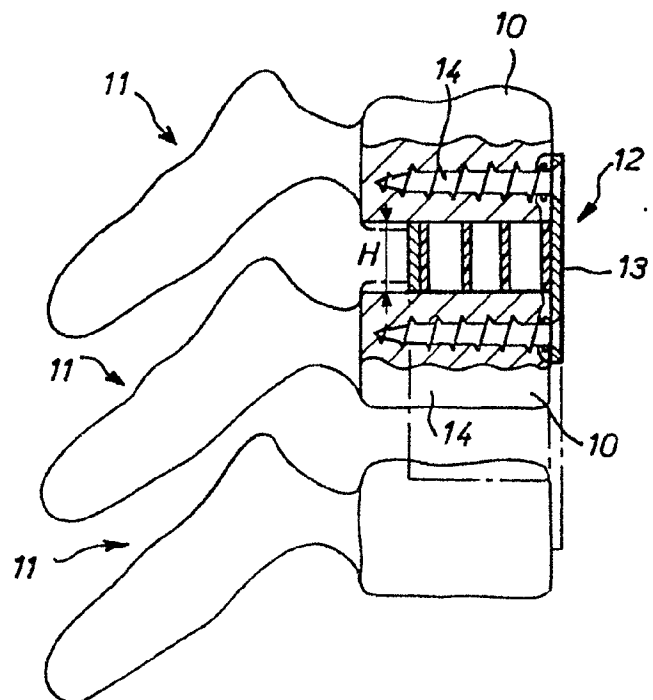


FIG. 5

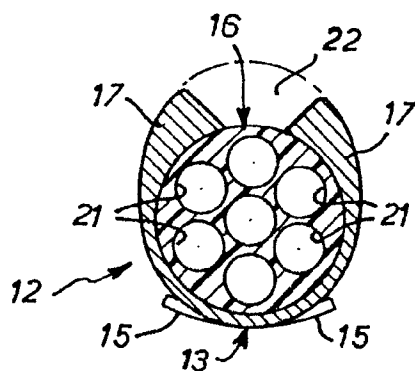
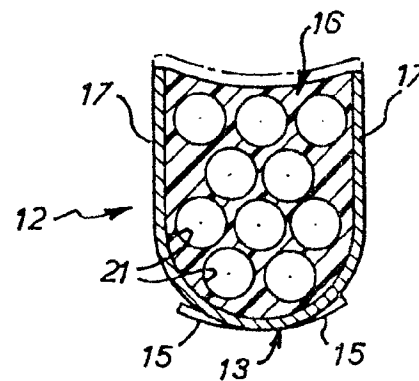


FIG. 6





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DOCUMENTS CONSIDERES COMME PERTINENTS			
Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes	Revendication concernée	CLASSEMENT DE LA DEMANDE (Int. Cl. 4)
X	GB-A-2 083 754 (REZAIAN) * Figures; page 1, lignes 55-105 *	1,2	A 61 F 2/44
A	--- US-A-3 426 364 (LUMB)		
A	--- US-A-3 486 505 (MORRISON)		
A	--- DE-A-2 547 816 (FEILD) -----		
			DOMAINES TECHNIQUES RECHERCHES (Int. Cl. 4)
			A 61 F A 61 B
Le présent rapport de recherche a été établi pour toutes les revendications			
Lieu de la recherche LA HAYE		Date d'achèvement de la recherche 13-01-1986	Examineur STEENBAKKER J.
CATEGORIE DES DOCUMENTS CITES			
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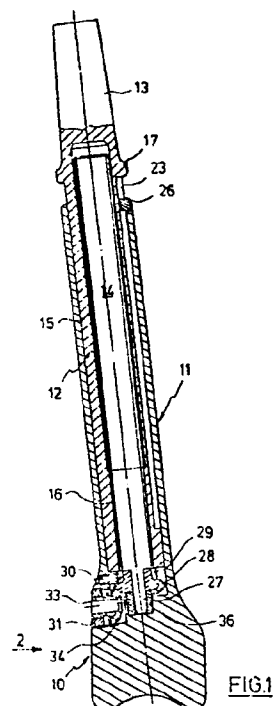
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Endoprothese für femorale oder tibiale Gelenkknochenteile und angrenzende Knochenabschnitte.

Endoprothese für femorale oder tibiale Gelenkknochenteile und angrenzende femorale oder tibiale Knochenabschnitte, mit einem femoralen Hüftgelenkteil und/oder einem femoralen Kniegelenkteil und/oder einem tibialen Kniegelenkteil und einem den Knochenabschnitt ersetzenden Knochenersatzteil, das aus zwei teleskopisch zusammenwirkenden Stangenteilen besteht, wobei ein Stangenteil eine Gewindespindel (14) aufweist, mit der eine Spindelmutter am anderen Stangenteil zusammenwirkt zur Längenverstellung des Knochenersatzteils, wobei die Spindelmutter von einer längeren Hülse (12) mit Innengewinde (16) gebildet ist, die in einer äußeren mit dem Gelenkteil (10) verbundenen Hülse (11) teleskopisch verschiebbar ist, die innerhalb der Spindelmutterhülse liegende Gewindespindel axial fest, jedoch drehbar im Gelenkteil gelagert ist und über ein Winkelgetriebe (28, 34) mit einem Antriebszapfen verbunden ist, der drehbar im Gelenkteil gelagert ist.



EP 0 290 767 A1

Endoprothese für femorale oder tibiale Gelenkknochenteile und angrenzende Knochenabschnitte

Die Neuerung bezieht sich auf eine Endoprothese für femorale oder tibiale Gelenkknochenteile und angrenzende femorale oder tibiale Knochenabschnitte nach dem Oberbegriff des Anspruchs 1.

Aus der DE-PS 3 205 577 ist eine Tumorendoprothese bekanntgeworden, bei der die Gelenkteile über eine konische Steckverbindung mit einem Verlängerungsstück bzw. einem Anschlußstück verbindbar sind. Die Konen der Prothesenteile bilden eine selbsthemmende Verbindung. Da das Knochenersatzteil aus einem Verlängerungsstück und einem in den Knochen einsetzbaren getrennten Anschlußstück zusammengesetzt ist, kann durch einen Satz Verlängerungsstücke abgestufter Länge eine relativ feine Anpassung an unterschiedlich lange zu ersetzende Knochenabschnitte vorgenommen werden bei einem minimalen Lageraufwand. Die selbsthemmende Konusverbindung erzeugt eine ausreichend feste Haltekraft gegen ein Auseinanderbewegen der Teile. Außerdem kann sie ein erhebliches Drehmoment übertragen.

Die bekannte Endoprothese ist nur durch Einsetzen verschieden langer Verlängerungsstücke oder Gelenkteile in ihrer Länge veränderbar. Dies bedeutet jedoch im Fall der Verlängerung einen erneuten operativen Eingriff. Bei im Wachstum betroffenen Patienten müßte ggf. mehrfach eine Operation vorgenommen werden, falls das zu versorgende Bein an das gesunde Bein in seiner Länge angepaßt werden soll.

Es ist daher auch bereits vorgeschlagen worden, eine Tumorendoprothese stufenlos in ihrer Länge verstellbar und damit den operativen Eingriff weniger schwerwiegend zu gestalten. Die hierfür vorgesehene Endoprothese besteht aus zwei teleskopisch zusammenwirkenden Stangenteilen. Ein rohrförmiges Stangenteil ist zum Beispiel einteilig mit dem Gelenkteil ausgebildet und zum Beispiel mit einem Außenkonus versehen zur Aufnahme einer Kugel für ein Hüftgelenk. Das Stangenteil lagert drehbar eine Mutter, mit der eine Gewindespindel als zweites Stangenteil zusammenwirkt. Am äußeren Ende der Gewindespindel kann zum Beispiel ein Kniegelenkteil angebracht sein. Die Spindelmutter weist eine äußere Kegelverzahnung auf, so daß sie mit einem ein Kegelrad aufweisenden Werkzeug, wie es in Verbindung mit Bohrfuttern oder dergleichen bekanntgeworden ist, verdreht werden kann.

Die zuletzt beschriebene Endoprothese weist einige Nachteile auf. Zwischen den beiden Stangenteilen besteht ein abrupter Übergang wodurch es zu einer Beeinträchtigung für den Patienten und sogar zu einer Weichteilschädigung kommen

kann. Die Gewindespindel liegt unmittelbar in den Weichteilen, so daß diese in die Gewindegänge einwachsen und somit eine Verstellung der Gewindespindel behindern können. Umgekehrt verursacht eine Verstellung der Gewindespindel in diesem Falle eine Weichteilschädigung. Der Verstellantrieb für die Gewindespindel liegt zwischen den Enden der Endoprothese und ist daher mehr oder weniger von Weichteilen umgeben. Eine postoperative Längenverstellung der Endoprothese erfordert daher einen erneuten, relativ weitgehenden Eingriff.

Der Neuerung liegt daher die Aufgabe zugrunde, eine in der Länge verstellbare Endoprothese zu schaffen, die auch postoperativ einfach verstellbar ist und weder während dieser Verstellung noch im Gebrauch eine Weichteilschädigung verursacht.

Diese Aufgabe wird durch die Merkmale des Kennzeichnungsteils des Anspruchs 1 gelöst.

Bei der neuerungsgemäßen Endoprothese ist die Spindelmutter von einer längeren Hülse mit Innengewinde gebildet, die in einer mit dem Gelenkteil verbundenen äußeren Hülse teleskopisch verschiebbar ist. Die innerhalb der Spindelmutterhülse liegende Gewindespindel ist axial fest, jedoch drehbar im Gelenkteil gelagert und über ein Winkelgetriebe mit einem Antriebszapfen verbunden, der drehbar im Gelenkteil gelagert ist.

Die äußere Hülse und die Spindelmutterhülse bilden bei der neuerungsgemäßen Endoprothese zwei teleskopisch ineinander verschiebbare Rohre. Die Unregelmäßigkeit im Außendurchmesser des Knochenersatzteils liegt mithin nur in der Differenz der Außendurchmesser von äußerer Hülse und Spindelmutterhülse. Diese ist verhältnismäßig gering und verursacht keine Weichteilschäden. Während der Verstellung der Endoprothese findet ausschließlich eine Axialverstellung statt, die sich ohne Schaden für den Patienten einfach durchführen läßt. Neuerungswesentlich ist ferner, daß der Winkeltrieb im Gelenkteil der Endoprothese liegt. Sowohl im Kniegelenkbereich als auch im Hüftgelenkbereich liegen größere Partien mit relativ geringer Weichteildeckung vor, so daß durch eine einfache Stichinzision ein Zugang zum Winkelgetriebe erhalten wird. Es ist daher lediglich eine örtliche Betäubung notwendig, um eine Längenänderung der Endoprothese vorzunehmen. Daher kann eine Längenänderung in relativ kurzen Zeitabständen erfolgen, ohne den Patienten zu stark zu belasten.

Bei der neuerungsgemäßen Prothese liegen mithin keine großen Durchmessersprünge vor, vielmehr sind - der Anatomie folgend - weiche Übergänge geschaffen. Auch scharfe Kanten, die zu einer Weichteilschädigung führen, sind vermieden.

Der Verstellmechanismus ist bei der neuerungsgemäßen Prothese gewebeschonend integriert und führt bei seiner Betätigung ebenfalls nicht zu einer Weichteilschädigung.

Die neuerungsgemäße Endoprothese kann einen gesamten Ober-oder Unterschenkelknochen ersetzen. Sie kann jedoch auch ein Gelenkteil und einen angrenzenden Knochenabschnitt ersetzen. In diesem Fall kann mit dem Knochenersatzteil ein Knochenanschlußstück verbunden werden zur Befestigung an einem gesunden Knochenabschnitt. Die Verbindung zwischen Endoprothese und Anschlußstück kann über eine selbsthemmende Konusverbindung erfolgen. Beim Ersatz eines gesamten Knochens kann die neuerungsgemäße Endoprothese ebenfalls einen Innen-oder Außenkonus aufweisen zur Verbindung mit einem Gelenkteil, das einen Außen-oder Innenkonus aufweist.

Um eine Drehung der Spindelmutterhülse zu vermeiden, sieht eine Ausgestaltung der Neuerung vor, daß die äußere Hülse einen nach innen weisenden, vorzugsweise am Ende angebrachten Vorsprung aufweist, der in einer Längsnut der Mutterhülse eingreift. Diese Nut kann nach einer weiteren Ausgestaltung der Neuerung am inneren Ende einen in Umfangsrichtung versetzten Endabschnitt aufweisen, der durch einen in Umfangsrichtung verlaufenden Nutabschnitt mit der Längsnut verbunden ist. Auf diese Weise ist die Spindelmutterhülse in der äußersten ausgefahrenen Stellung axial gesichert.

Die Gewindespindel ist, wie bereits erwähnt, drehbar im Gelenkteil aufgenommen. Hierzu kann gemäß einer Ausgestaltung der Neuerung eine Lagerbuchse vorgesehen sein, die einen Lagerzapfen der Gewindespindel aufnimmt. Das Winkelgetriebe besteht vorzugsweise aus zwei Kegelrädern, von denen eines mit der Gewindespindel und das andere mit dem Antriebszapfen verbunden ist. Das Kegelrad der Gewindespindel kann beispielsweise auf dem erwähnten Zapfen sitzen, wobei die Stirnseite mit der zugekehrten Stirnseite der Lagerbuchse zusammenwirkt. Auch der Antriebszapfen kann in der Lagerbuchse gelagert sein, die auch eine Begrenzung des Antriebszapfens aus der Lagerbuchse heraus vorsieht. Die Lagerbuchse kann ihrerseits in das Gelenkteil eingeschraubt sein.

Eine eingestellte Relativlage der beiden Stangenteile der neuerungsgemäßen Endoprothese soll nach Möglichkeit nicht verändert werden. Daher sieht eine Ausgestaltung der Erfindung vor, daß zwischen dem Kegelrad auf der Gewindespindel und einer radialen Schulter der Gewindespindel eine umlaufende Nut gebildet ist, die mindestens eine Vertiefung aufweist und ein Gewindestift in die Nut eingreift. Mit Hilfe des Gewindestiftes kann die Gewindespindel gegen Drehung gesichert werden.

Die Neuerung wird nachfolgend anhand von Zeichnungen näher erläutert.

Fig. 1 zeigt teils in Seitenansicht, teils im Schnitt eine Endoprothese nach der Neuerung.

Fig. 2 zeigt eine Seitenansicht des unteren Teils der Prothese nach Fig. 1 in Richtung Pfeil 2.

Fig. 3 zeigt vergrößert einen Schnitt durch den tibialen Abschnitt einer Endoprothese entsprechend Fig. 1, jedoch in abgewandelter Ausführung.

Fig. 4 zeigt eine Seitenansicht teilweise im Schnitt eines Gelenkteils zur Verbindung mit der Endoprothese nach Fig. 1.

Fig. 5 zeigt eine Seitenansicht des unteren Teils einer Hülse nach Fig. 1.

Fig. 6 zeigt einen Schnitt durch die Darstellung nach Fig. 5 entlang der Linie 6-6.

Bevor auf die in den Zeichnungen dargestellten Einzelheiten näher eingegangen wird, sei vorangestellt, daß jedes der beschriebenen Merkmale für sich oder in Verbindung mit Merkmalen der Ansprüche von neuerungswesentlicher Bedeutung ist.

Die in Fig. 1 dargestellte Endoprothese besitzt ein femorales Kniegelenkteil 10, auf dessen Aufbau im einzelnen nicht eingegangen werden soll. Es wirkt zusammen mit einem nicht gezeigten tibialen Kniegelenkteil. Mit dem Gelenkteil 10 ist eine äußere Hülse 11 verbunden. Teleskopisch innerhalb der Hülse verschiebbar ist eine Spindelmutterhülse 12, die am äußeren Ende einen Außenkonus 13 aufweist. Innerhalb der Hülse 12 befindet sich eine Gewindespindel 14.

Der Aufbau der Mutterhülse 12 geht aus den Figuren 3, 4 und 6 näher hervor. Die Innenbohrung 15 der Hülse 12 weist nur nahe dem offenen Ende einen Gewindeabschnitt 16 auf. Der Durchmesser der Bohrung 15 ist etwas größer als der Innendurchmesser des Gewindeabschnitts 16. Unterhalb des Konus 13 ist ein Bund 17 geformt. Der Konus 13 dient zum Beispiel zur Aufnahme des Innenkonus 18 eines femoralen Hüftgelenkteils 19 gemäß Fig. 4. Die Konen 13, 18 wirken selbsthemmend zusammen. Eine Nase 20 des Gelenkteils 19 wirkt mit einer entsprechenden Ausnehmung am Konus 13 zusammen und legt somit die Drehlage der beiden Teile zueinander fest. Das Gelenkteil 19 weist einen weiteren Konus 21 auf zur Aufnahme einer Gelenkkugel. Anstelle des Gelenkteils 19 kann auch ein Anschlußstück bzw. ein Verlängerungsstück treten. Im ersteren Fall würde der Konus 13 durch einen Innenkonus ersetzt, der mit einem Außenkonus eines nicht gezeigten Anschlußstücks zusammenwirkt.

Die Hülse hat an der Außenseite eine achsparallele Längsnut 23. Sie endet in einem in Umfangsrichtung sich erstreckenden Nutabschnitt 24, der am anderen Ende in einen achsparallelen Längsnutabschnitt 25 mündet. Wie aus Fig. 1 ersichtlich, besitzt die äußere Hülse 11 am freien

Ende einen radial nach innen gerichteten Vorsprung 26, der in die Längsnut 23 eingreift. Beim Einführen der Mutterhülse 12 in die äußere Hülse 11 gelangt der Vorsprung 26 zunächst in den unteren Nutabschnitt 25. Anschließend wird die Hülse 12 um einen gewissen Betrag gedreht (Vierteldrehung) bis der Vorsprung in die Nut 23 eintreten kann.

Die Gewindespindel 14 ist am unteren Ende mit einem Zapfen 27 versehen, auf den drehfest ein Kegelrad 28 aufgeschoben ist. Der Zapfen 27 ragt jedoch über das Kegelrad 28 hinaus. Im Kegelrad 28 sind einzelne in Umfangsrichtung versetzte Vertiefungen 29 vorgesehen. In Fig. 1 ist ein in das Gelenkteil 10 eingesetzter Gewindestift 30 zu erkennen, der in eine Nut ragt, die zwischen dem Kegelrad 28 und dem unteren Ende der Hülse 12 gebildet ist. Im gezeigten Fall greift dieser Gewindestift 30 in eine Vertiefung 29 ein und verhindert mithin eine Verdrehung der Gewindespindel 14.

In eine Bohrung des Gelenkteils 10 ist eine Lagerbuchse 31 eingeschraubt. Sie dient zur Lagerung eines Zapfens 33, der am inneren Ende ein Kegelrad 34 aufweist, das mit dem Kegelrad 28 der Gewindespindel 14 kämmt. Der Zapfen weist einen Innensechskant auf, in den ein entsprechendes Drehwerkzeug eingreifen kann.

Der über das Kegelrad 28 überstehende Teil des Zapfens 27 greift in eine Lagerbuchse 36 ein, die im Gelenkteil 10 angeordnet ist. Das Kegelrad 28 gleitet mithin auf der zugekehrten Stirnseite der Lagerbuchse 36.

Man erkennt aus Fig. 1, daß eine Drehung des Antriebszapfens 33 zu einer Drehung des Kegelrads 34 führt, das seinerseits das Kegelrad 28 und damit die Gewindespindel 14 in Drehung versetzt. Dadurch wird die Mutterhülse 12 axial bewegt und gleitet beispielsweise aus der äußeren Hülse 11 heraus. Man erkennt ferner, daß die Lage des Innengetriebes derart ist, daß der Antriebszapfen 33 sehr leicht erreichbar ist. Im Bereich des Knies liegt bekanntlich eine geringe Weichteildeckung vor.

Der Antriebsmechanismus gemäß Fig. 3 unterscheidet sich in einigen Punkten von dem nach Fig. 1. Soweit mit Fig. 1 gleiche Teile verwendet werden, sind diese in Fig. 3 mit gleichen Bezugszeichen versehen, die jedoch zusätzlich den Index a tragen.

In einem erweiterten Abschnitt der Gewindehülse 12a ist eine Hülse 50 eingeschoben und durch Schweißung befestigt. Sie ist mit dem Gewindeabschnitt 16a versehen, der mit dem Gewinde der Gewindespindel 14a zusammenwirkt. Aus Fig. 3 ist auch zu erkennen, daß die Gewindespindel aus Gewichts- und Ersparnisgründen hohl ist.

Die Bohrung des Schaftes 11 weist nahe dem Gelenkteil 10a eine Schulter 51 auf, auf der ein Ring 52 ruht, der mit Hilfe eines Stifts 53, der durch die Wandung des Schaftes 11a hindurchgeführt ist, festgelegt ist. In die obere Stirnseite des Ringes 52 ist eine Gleitscheibe 53 bündig eingelassen. Der zylindrische Zapfen 27a der Gewindespindel 14a erstreckt sich durch die Bohrung des Ringes 52. Oberhalb des Zapfens 27a ist ein Ringbund 54 an die Gewindespindel angeformt. Der Ringbund befindet sich innerhalb eines freien Raums 55, der durch eine Durchmessererweiterung der Bohrung der Hülse 12a gebildet ist unterhalb der Hülse 50. Die Gewindespindel 14a stützt sich mithin über den Ringbund 54 auf dem Ring 52 ab, der mithin die axiale Belastung auf das Gelenkteil 10a überträgt.

Das Zahnrad 28a ist mit Hilfe von Stiften 56 am Zapfen 27a festgelegt. Es ist frei von axialen Belastungen. Es kämmt mit dem Zahnrad 34a, das einteilig mit dem Zapfen 33a geformt ist. Der Zapfen 33a ist in der Gewindehülse 31a drehbar gelagert und weist eine Sechskantausnehmung 35a für ein Drehwerkzeug auf. Die Rückseite des im Durchmesser größeren Zahnrads 34a sichert das Zahnrad 34a bzw. den Zapfen 33a gegen eine axiale Bewegung nach außen. Gegenüber dem Zapfen 33a ist ein Lagerstift 57 mittig in das Zahnrad 34a eingelassen zur verbesserten axialen Lagerung des Zahnrads 34a.

Im Gelenkteil 10a ist ein im Außendurchmesser gestufter Feststellstift oder eine Feststellschraube 58 von einer entsprechenden Gewindebohrung aufgenommen. Das innere Ende hält ein im Querschnitt U-förmiges Ringsegment zur Festsetzung des Zahnrads 28a. Das Ringsegment ermöglicht eine Verteilung der Druckkraft über einen gewissen Umfangsbereich des Zahnrads 28a.

Ansprüche

1. Endoprothese für femorale oder tibiale Gelenkknochenteile und angrenzende femorale oder tibiale Knochenabschnitte, mit einem femoralen Hüftgelenkteil und/oder einem femoralen Kniegelenkteil und/oder einem tibialen Kniegelenkteil und einem den Knochenabschnitt ersetzenden Knochenersatzteil, das aus zwei teleskopisch zusammenwirkenden Stangenteilen besteht, wobei ein Stangenteil eine Gewindespindel aufweist, mit der eine Spindelmutter am anderen Stangenteil zusammenwirkt zur Längenverstellung des Knochenersatzteils, dadurch gekennzeichnet, daß die Spindelmutter von einer längeren Hülse (12) mit Innengewinde (16) gebildet ist, die in einer äußeren mit dem Gelenkteil (10) verbundenen Hülse (11) teleskopisch verschiebbar ist, die innerhalb der

Spindelmutterhülse (12) liegende Gewindespindel (14) axial fest, jedoch drehbar im Gelenkteil (10) gelagert ist und über ein Winkelgetriebe (28, 34) mit einem Antriebszapfen (35) verbunden ist, der drehbar im Gelenkteil (10) gelagert ist.

Ende mit einem Ringsegment (59) versehen ist, das sich gegen einen zylindrischen Abschnitt des Zahnrads (28a) legt.

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2. Endoprothese nach Anspruch 1, dadurch gekennzeichnet, daß die äußere Hülse (11) einen nach innen weisenden, vorzugsweise am Ende angebrachten Vorsprung (26) aufweist, der in eine Längsnut (23) der Mutterhülse (12) eingreift.

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3. Endoprothese nach Anspruch 2, dadurch gekennzeichnet, daß die Nut (23) an ihrem inneren Ende einen in Umfangsrichtung versetzten Endabschnitt (25) aufweist, der durch einen in Umfangsrichtung verlaufenden Nutabschnitt (24) mit der übrigen Längsnut (23) verbunden ist.

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4. Endoprothese nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die Gewindespindel (14) an dem inneren Ende einen Lagerzapfen (27) aufweist, der von einer Lagerbuchse (36) im Gelenkteil (10) aufgenommen ist.

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5. Endoprothese nach Anspruch 4, dadurch gekennzeichnet, daß ein Kegelrad (28) auf dem Zapfen (27) aufgenommen ist, dessen Stirnseite mit der Stirnseite der Lagerbuchse (36) zusammenwirkt.

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6. Endoprothese nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß der Antriebszapfen (35) mit einem Kegelrad (34) versehen ist und in einer Lagerbuchse (31) gelagert ist, die eine Begrenzung (32) des Antriebszapfens (33) aus der Lagerbuchse heraus vorsieht.

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7. Endoprothese nach Anspruch 6, dadurch gekennzeichnet, daß die Lagerbuchse (31) in eine Gewindebohrung des Gelenkteils (10) eingeschraubt ist.

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8. Endoprothese nach einem der Ansprüche 4 bis 7, dadurch gekennzeichnet, daß zwischen dem Kegelrad (28) auf der Spindel (14) und einer radialen Schulter der Spindel (14) eine umlaufende Nut gebildet ist, die mindestens eine Vertiefung (29) aufweist und ein Gewindestift (30) in die Nut eingreift.

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9. Endoprothese nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß nur ein begrenzter, dem Winkelgetriebe benachbarter Abschnitt (16) der Mutterhülse (12) mit einem Innengewindeabschnitt versehen ist.

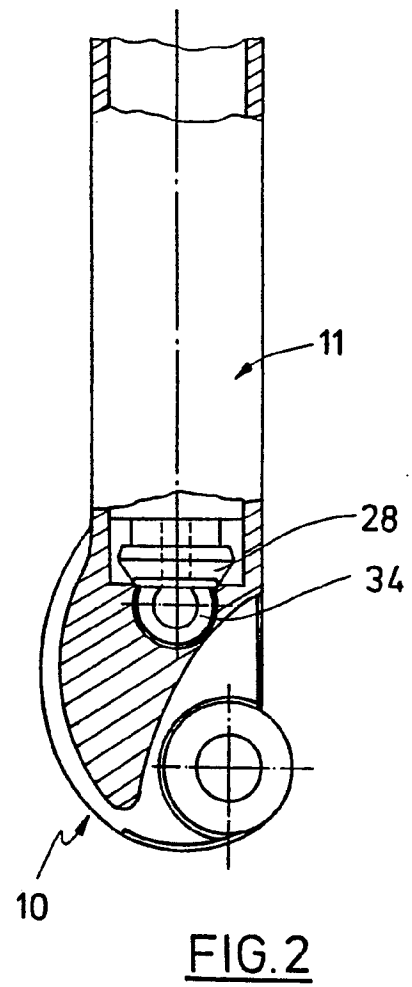
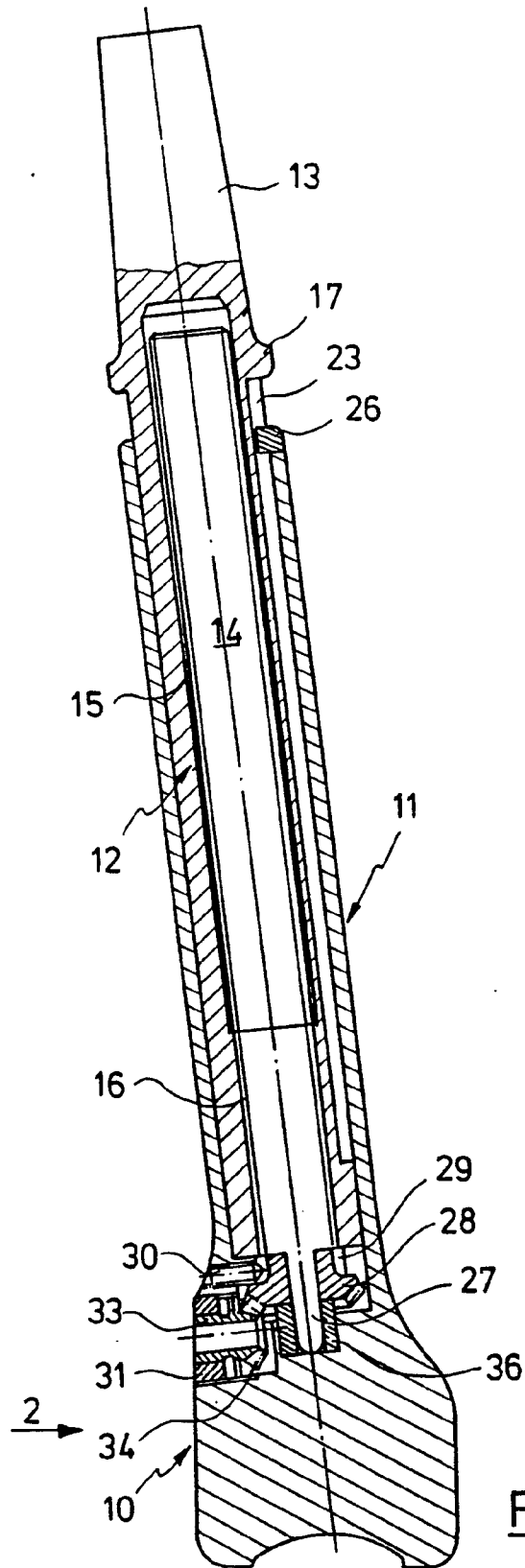
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10. Endoprothese nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die Gewindespindel (14a) einen Ringbund (54) aufweist, der mit einem Lagerring (52, 53) im Inneren des Gelenkteils (10a) zusammenwirkt.

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11. Endoprothese nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß ein im Gelenkteil (10a) angeordneter Feststellstift (58) am inneren

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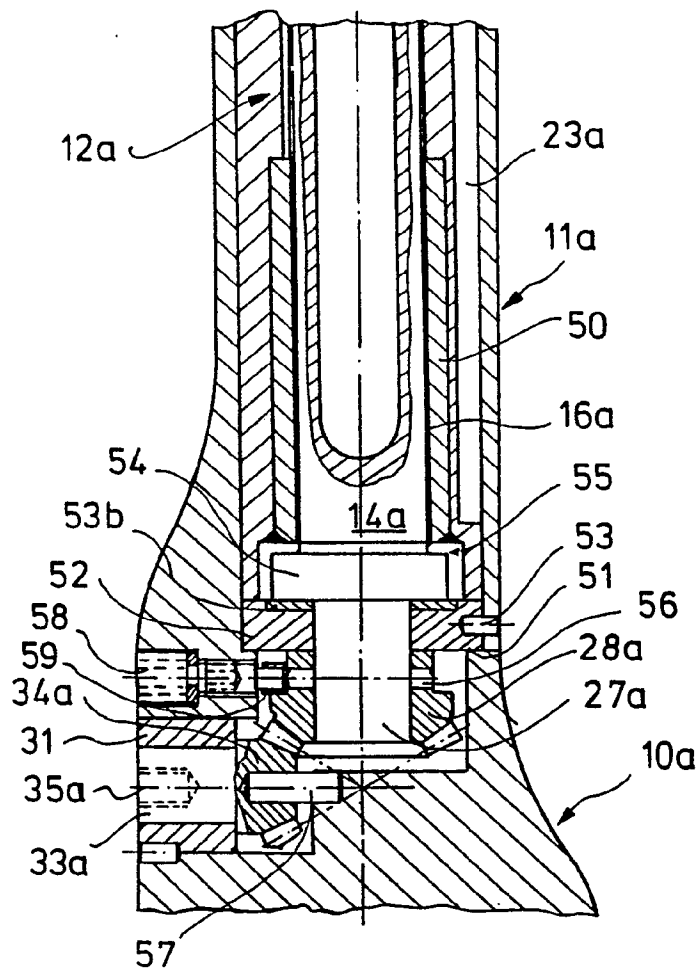


FIG. 3

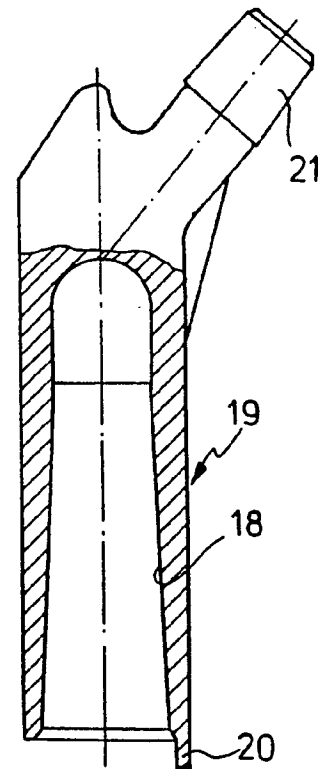


FIG. 4

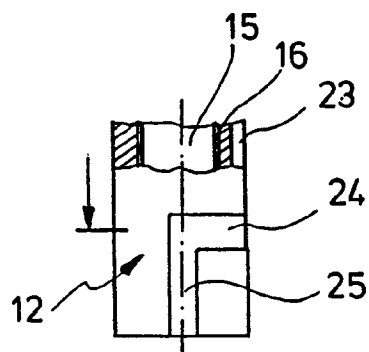


FIG. 5

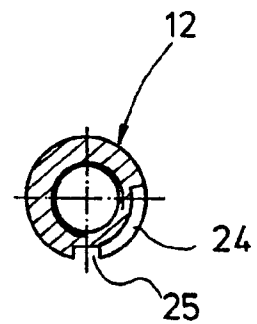


FIG. 6



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EP 88 10 4938

EINSCHLÄGIGE DOKUMENTE			
Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int. Cl.4)
X	EP-A-0 144 667 (WRIGHT MANUFACTURING CO.) * Figuren 1,5; Ansprüche 1,2 *	1	A 61 F 2/28 A 61 F 2/36 A 61 F 2/38
A	---	2,4	
A	US-A-4 384 373 (K.M. SIVASH) * Figuren 2,3 *	1	
A	---		
A	GB-A-2 137 884 (NATIONAL RESEARCH DEVELOPMENT CORP.) * Figur 2 *	1,2	
A	---		
A	DE-A-3 336 004 (S + G IMPLANTS GMBH) * Figuren 1-5 *	1	
D,X	---		
D,X	DE-U-8 706 999 (HOMEDICA GMBH) * Ansprüche 1-11 *	1-11	

Der vorliegende Recherchenbericht wurde für alle Patentansprüche erstellt			RECHERCHIERTE SACHGEBIETE (Int. Cl.4) A 61 F 2/00
Recherchenort BERLIN		Abschlußdatum der Recherche 01-08-1988	Prüfer KANAL P K
KATEGORIE DER GENANNTEN DOKUMENTE X : von besonderer Bedeutung allein betrachtet Y : von besonderer Bedeutung in Verbindung mit einer anderen Veröffentlichung derselben Kategorie A : technologischer Hintergrund O : nichtschriftliche Offenbarung P : Zwischenliteratur T : der Erfindung zugrunde liegende Theorien oder Grundsätze E : älteres Patentdokument, das jedoch erst am oder nach dem Anmeldedatum veröffentlicht worden ist D : in der Anmeldung angeführtes Dokument L : aus andern Gründen angeführtes Dokument & : Mitglied der gleichen Patentfamilie, übereinstimmendes Dokument			

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Fusion cage for bone joints.

A fusion basket (10) having an external, substantially continuous helical V-thread (12) by which it can be screwed into a bore after first forming in the bore mating female threads that bite into the cancellous regions.. Mating of the threads ensures that the fusion basket remains securely in place without compressing or splitting the recipient bone. Eventually, the ingrowth of bone through perforations (13) in the valley (14) of the thread forms a permanent interconnection between the two bony structures. When used to create bone ingrowth between adjacent vertebrae, the V-thread fusion basket is implanted in pairs on opposite sides of the disc space.

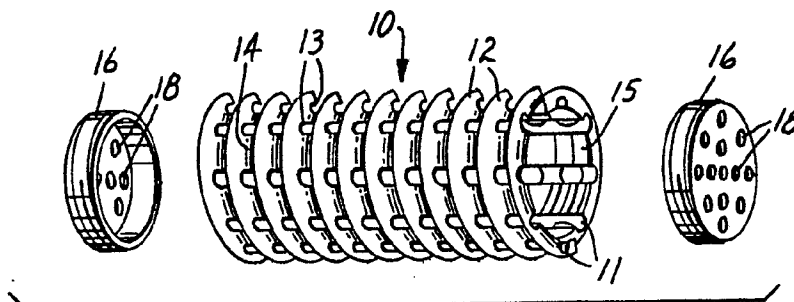


FIG. 1

FUSION CAGE

The invention concerns method and apparatus for fusing two adjacent bony structures such as a bone joint, especially adjacent vertebrae of the spine.

BACKGROUND OF THE INVENTION

Subsequent to injury, disease or other degenerative disorder, the disc, a ligamentous cushion between vertebrae, may undergo a painful deterioration. The disc shrinks and flattens out, and the distance between the vertebral bodies begins to collapse. Subsequently, there may be a progressive degeneration leading to mechanical instability, where painful translocations occur between adjacent vertebrae. The movement-induced pain may be so disabling that in many such cases, the segmental motion must be eliminated. Thus, rigid fusions may be the only present means to stop the translocations and relieve the pain.

It is generally held that successful fusions demand a contiguous growth of bone to create a solid mass that will unite the movable elements into one unit. Otherwise, the fusion cannot achieve the tasks of pain reduction, maintenance of intervertebral height, and immobility of the segment. When fusion bone is first placed, it is soft and movable, having no cohesive strength. Therefore a variety of appliances have been developed that attempt to hold the segments quite still under conditions of normal spinal activity and daily stress. Bone graft material is placed between the segments, the outer or cortical surfaces of which have been removed or deeply scarified so as to promote the ingrowth of the graft into these recipient sites. Thus positioned, the bone graft slowly unites the segments. Such an appliance is not meant to permanently secure immobility of the segments. Bone ingrowth is required for this.

Dependency upon such an appliance as the sole stabilizer is ultimately unsuccessful due to the development of a mechanical gap or transition between the bone and the appliance, leading to structural failure of the bone and adjacent connective tissue. Such failure is seen in fractures, erosion, and absorption of bone with potential further collapse. The pain may also become progressively disabling.

Approximately 150,000 lumbar spinal fusions were performed in the USA during 1987, as reported by the American Hospital Association. There are many methods for intervertebral fusion. The most successful have achieved a success rate of

about 90% in random cases. However, several of these techniques, especially those requiring complex appliances, are difficult to master and are hazardous to nerve and vessel structures normally lying close to the involved bones.

From a biomechanical point of view, the most important location of a spinal fusion is at the mechanical center of rotation between the vertebrae. This point is centered within the disc space. Therefore, an interbody fusion is the most rigid and thus the most sought after method among surgeons. Current methods of interbody fusions are, however, the most hazardous of all spinal fusion methods.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions. Typically, a plug, dowel, or segment of bone is driven tightly into a cavity carved inside the interbody, intradiscal space. Since there must be a bone-to-bone bridge created during the fusion process, connective tissue and discal tissue must be removed. Therefore, deep cuts within the bone must penetrate into the softer, cancellous region to promote bone growth across the space.

Intervertebral fusions using circular bone grafts have been reported in the orthopedic and neurosurgical literature for some years. B. R. Wiltberger in a paper published in *Clinical Orthopedics*, Vol. 35, pp. 69-79, 1964, reviewed various methods of intervertebral body fusion using posterior bone dowels driven firmly into a suitably smaller hole between the adjacent vertebrae. Upon doing so the dowel can split or crack or collapse. The stretched bone might also split and it can be compressed by the dowel to the point that it will not grow normally due to collapse of formerly open pores or vascular channels. If this occurs, there may be a late absorption of surrounding bone and the dowel might loosen, with a renewed danger of expulsion. See also a two-page brochure from Neurological Surgery Associates of Cincinnati, Inc. entitled "Posterior Lumbar Interbody Fusion Made Simple" which shows, after the bone dowel placement, the "(a)pplication of 5 mm dacron suture around spinous processes."

U.S. Patent 4,501,269 (Bagby) describes a surgical procedure for stabilizing the cervical spine of a horse and says that the procedure "is applicable to any human or animal joint formed by opposed contiguous bony surfaces which are covered and separated by intervening cartilage and are surrounded by ligaments which resist expansion of the joint. Specific examples of such joints are a spinal joint between adjacent vertebrae or the ankle joint. The process was developed to immediately stabilize the joint and to further promote ultimate

bone-to-bone fusion...The implanted structure is in the form of a perforated cylindrical bone basket which can be filled with bone fragments produced during the preparation of the joint. These bone fragments provide autogenous tissue to promote bone growth through the basket, as well as around it.

"The process involves the initial steps of surgically accessing the joint and removing intervening cartilage located between the contiguous bony surfaces. A transverse cylindrical opening is then bored across the contiguous bony surfaces. Immediate stabilization is achieved by driving into the cylindrical opening a hollow basket having a rigid perforated cylindrical wall whose outside diameter is slightly greater than the inside diameter of the cylindrical opening. The implanting of the basket spreads the bony surfaces apart in opposition to the resistance to expansion of the joint provided by the surrounding ligaments." (Col. 2, lines 26-55).

Vich, J. Neurosurg Vol. 63, pp. 750-753 (1983) describes a means for cervical spine fusion, using an anterior approach, by surgically implanting a cylindrical bone graft. "Screw threads are placed in the graft with a small, previously sterilized die. The grooves of the thread can be made as deep as required. The vertebral cervical bodies are prepared according to Cloward's technique. After a cylindrical bed has been drilled in the appropriate intervertebral bodies, the graft is screwed into place with instruments especially developed for this purpose." (P. 750). The Fig. 2 legend points out that a threaded graft dowel has a larger contact surface than a plain dowel and a greater resistance to pressure and sliding.

An additional desirable effect of an intervertebral fusion is the restoration or maintenance of a normal intervertebral spacing. Spreading devices are generally required in order to restore all or a part of the normal intradiscal height, in the process of placing the fusion material or appliance. When the procedure is performed using the commonly employed posterior approach, a variety of spreaders may be placed between various posterior bony elements normally attached to the vertebrae, such as, dorsal spinous processes or laminae. Using such spreaders, a forward tilt or wedging of the discal space occurs, with the posterior aspect of the space becoming more open than the anterior. When a bone graft of any shape is driven into a cavity that is wedged more open posteriorly between two opposing movable vertebrae, there is a strong propensity for the graft to be retropulsed during the postoperative recovery period as a result of to and fro movement between the opposing vertebrae. Thus, to aid in the prevention of graft expulsion, it would be desirable to have the cavity either maintain parallelism or be slightly narrower

at its most posterior portion. Ventral to this cavity, the stout ligamentous disc anulus remains and prevents ventral migration of the graft into the retroperitoneal space. Further, there is value in restoring the original spinal lordotic curve, as the fusion grows; this requires that the cavity and the interbody fusion element be placed to promote a normal spinal anatomical position, that is, without wedging of the space in either direction.

BRIEF SUMMARY OF THE INVENTION

The invention provides a fusion basket or cage which, like the fusion basket of Bagby, is a perforate rigid cylinder that can be surgically inserted into a bore that has been formed in two adjacent bony structures such as two vertebrae. The fusion cage is then packed with bone chips or other bone-inducing substance, thus inviting ingrowth of live bone. The fusion cage of the invention differs from the fusion basket of Bagby by an external, substantially continuous helical V-thread by which it can be screwed into the bore, after first forming mating female threads in the bore. Mating of the threads ensures that the fusion basket remains securely in place, there being much less danger of splitting or compression atrophy of the recipient bone. Eventually, the ingrowth of bone through perforations in the valley of the thread forms a permanent interconnection between the two bony structures.

By V-thread is meant that the crown of the thread is sharp, although its valley preferably is blunt or rounded to permit the mating peaks of the female threads to have adequate strength. When the angle of the V-thread at its crown is about 60° , a preferred range of radii for the fillet in the valley is from 0.35 to 0.75 mm. The angle at the crown of the V-thread should be no more than 90° , because a sharper thread would increase the exposed interface surface of bone relative to the implant, thus increasing the opportunity for ingrowth. However, the angle at the crown should be at least 45° , because the pitch would be undesirably small if the angle were smaller. An unduly small pitch would entail weak female bone threads and create a danger of cross threading.

The perforations should be as large as possible as long as the fusion basket has adequate structural strength. When the surface of the fusion basket is projected onto the inner face of a cylinder, the projected perforations should comprise from 30% to 60% of the projected area, preferably about 50%. Individual apertures should be at least one mm both axially and transversely to permit good ingrowth of fresh bone, whereas the fusion basket might be unduly weakened if the apertures were

substantially more than 2 mm axially and 3 mm transversely when the angle of the V-thread at its crown is about 60°.

The novel fusion basket preferably is fitted with end caps, a first of which may be in place before the fusion basket is screwed into the recipient bone, and thus should have a maximum diameter no greater than the minor diameter of the V-thread of the fusion basket. The first end cap retains the bone-inducing substance when it is packed into the fusion basket. The open end of the fusion basket may then be closed with a second end cap to hold the bone chips securely in place. The end caps may be imperforate but preferably have substantially the same perforation as does the fusion basket to permit bone or other tissue ingrowth through the end caps. However, end caps may not be necessary or, if used, they can be made of biodegradable material, even when the fusion basket is not.

Currently the novel V-thread fusion basket preferably is made of implantable-grade stainless steel. Titanium and ceramics are also useful, as are super-strength polymers or composites of polymers and high-strength filaments such as super-high-density polyethylene, glass, or graphite. Non-metallic composites have the preferred ability to pass x rays or magnetic beams without distortion, thus enhancing the preparation of scan images as compared to metallic fusion baskets. The fusion basket can be biodegradable, because it no longer is needed after the bone ingrowth has matured. When the fusion basket is not biodegradable, it can remain in place permanently after the ingrowth has taken place, in contrast to the need to remove many types of metallic supports or appliances that have heretofore been used to promote rigid fusions.

Useful bone-inducing substances include bone chips and bone substitutes or synthetic material, with or without bone activating matter, such as hydroxyapatite, bone morphologic protein, bone growth factor, or cartilage activation factor. Instead of being mixed with the bone-inducing substance, bone-activating matter can be coated onto the novel fusion basket, e.g., after being microencapsulated in a wax. When the fusion basket is made of an organic material, bone activating matter can be combined with the organic material before it is formed into the fusion basket.

For implantation between vertebrae of a person's lower back, two sizes of the novel fusion basket should suffice, one having a V-thread major diameter of 16 mm and the other a major diameter of 12 mm. Because the anterior-posterior dimension of a typical lower lumbar vertebra is about 30 mm, the length of the fusion basket preferably does not exceed 25 mm but is at least 20 mm in

length to give sufficient contact as well as a good platform when implanted in pairs.

The crown of the V-thread of the novel fusion basket preferable is continuous, both for strength and for ease of insertion into the threaded bore. Preferably the V-thread has from 3 to 8 turns per cm. A smaller turn ratio may result in an undesirably large thread depth, penetrating too deeply into the cancellous bone. A larger turn ratio may unduly restrict the size of the perforations.

The novel V-thread fusion basket can be implanted for fusing adjacent bony structures by the following method: (a) forming in said bony structures a bore with a female thread that penetrates into their cancellous regions, (b) forming a rigid, perforate, cylindrical basket to have an external, substantially continuous helical V-thread that can mate with said female thread, (c) screwing the basket into said threaded bore, and (d) packing the basket with bone-inducing substance. When the bore to be formed in step (a) is to extend between adjacent vertebrae, there should be prior to step (a) the added step of spreading the vertebrae apart, preferably in a manner that maintains their parallelism, the fusion basket is implanted in pairs on opposite sides of the disc space.

The novel fusion basket should have a modulus of elasticity approximating that of the recipient bone, thus permitting it to flex along its length, consequently minimizing stresses at the bony interface between the graft and recipient bone. Although a fusion basket of substantially lower modulus of elasticity would provide the same desirable result, it might not have adequate structural strength.

The bore into which the V-thread fusion basket is to be inserted preferably is tapped by hand, using a slow motion to ensure against burning the bone. This freshens the bone margins of the bore so that if any bone had been burned by drilling to form the bore, it is now cut away slowly by hand. The tapping process is quite safe, in that the surgeon can feel the progress of the technique.

The V-thread fusion basket preferably is screwed by hand into the threaded bore, again permitting the surgeon to feel if the resistance is too great and that rethreading of the bore might be required. In contrast, a bone dowel typically is driven into a bore using a hammer, and in order to guard against an overly tight fit, the surgeon listens to the sound of the striking hammer and also monitors the degree of resistance.

When using the novel fusion basket to create bone ingrowth between adjacent vertebrae, the fusion basket should be implanted in pairs on opposite sides of the disc space. Each is held in place by its V-thread, biting into female threads that penetrate into the cancellous bone of the inter-

posed vertebral bodies. Gravity, muscle pull, and elastic recoil of the spread (or stretched) outer disc anulus together exert force against each of the fusion baskets. Thus the fusion baskets are held in place by compression forces between the adjacent vertebrae.

To prevent distraction forces from possibly dislodging the fusion baskets, e.g., when the patient forward flexes, thus separating the posterior margins of the adjacent vertebrae, the dorsal processes may be tied or wrapped together. By another technique, screws placed through the appropriate facet jackets limit both flexion and extension motions.

A novel interbody spreader in the form of a scissors jack has been developed to maintain a desirable parallel attitude between the adjacent vertebrae while the bore is drilled and then tapped by a novel instrument. Another instrument that has been developed for use in the implantation of the novel fusion basket is a tapping instrument for forming helical threads in a bore in recipient bone. This novel tapping instrument comprises a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and

a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus removed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the hollow shaft.

The portion of the pilot rod that projects beyond said other end of the hollow shaft preferably is threaded to carry detritus upwardly to the reservoir.

When using the novel tapping instrument to form female threads for an interbody fusion, the hollow shaft should have an odd number of scallops and cutting edges, preferably three because an odd number provides more equal removal of recipient bone on both sides of the bore than would an even number.

The novel tapping instrument and a novel wrench are illustrated in the drawing that also illustrates two V-thread fusion baskets of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawing, all figures of which are schematic,

Fig. 1 is an exploded isometric view of a first V-thread fusion basket of the invention and two perforated end caps;

Fig. 2 is an isometric view illustrating the formation of a body that can be cut to form a series of second V-thread fusion baskets of the invention;

Fig. 3 is an isometric view of a tap (partly cut away to reveal details of construction) for forming female thread in bores into which a V-thread fusion basket is to be inserted; and

Fig. 4 is an isometric view of a wrench for screwing a V-thread fusion basket into a threaded bore.

The fusion basket 10 of Fig. 1 was formed from a solid steel cylinder by drilling eight small, equally-spaced holes 11 in the axial direction, each hole being centered on a circle concentric with the axis of the cylinder. Then a large hole was drilled centered on the axis and having a radius substantially identical to that of the aforementioned circle. A V-thread 12 was then machined in the external surface of the cylinder, thus opening through that surface a perforation 13 extending through the rounded valley 14 of the V-thread at each crossing of the valley and one of the small holes 11. A screw thread 15 was then machined in the internal surface of the fusion basket to threadably receive an end cap 16 that has apertures 18 similar to those of a salt shaker. Snap-on end caps would also be useful.

In making a fusion basket by the technique described in the preceding paragraph, the small holes 11 could be enlarged to intersect each other, thus making it unnecessary to drill a central hole. Enlarged small holes would result in larger perforations 13.

Referring to Fig. 2, a series of fusion baskets can be made from a plurality of rods 22 of rectangular cross-section that can be continuously extruded and fed into each of eight keyways 23 in the surface of a mandrel 24. Simultaneously, a rod 26 of triangular cross-section is extruded, wrapped helically around the rectangular rods 22, and soldered or welded to each of the rectangular rods 22 at every crossing to provide an external V-thread. Upon emerging from the keyways, the resulting body is cut into individual fusion baskets each of which has a perforation 28 between adjacent turns of the V-thread-forming rod 26 wherever it bridges a gap between adjacent rectangular rods 22.

A fusion basket identical to that of Fig. 2 can be made from a hollow cylinder by machining an external V-thread and broaching a plurality of rectangular internal keyways.

Each of the fusion baskets of Figs. 1 and 2 could be made from a model by the lost-wax process.

The tapping instrument 30 of Fig. 3 has a hollow cylindrical shaft 31 with a T-handle 32 at one end and an external thread 33 at the other end.

Slidably received within the hollow shaft is a pilot rod 34, one end 35 of which protrudes beyond the hollow shaft 31 and slidably fits into a bore that has been drilled into the recipient bone. At the other end of the pilot rod is a knurled cap 35A. Projecting from the threaded end of the hollow shaft 31 are cutting teeth 36 that enlarge the bore to the minor diameter of the external thread 33 of the hollow shaft 31. The threaded end of the hollow shaft also is formed with three symmetrical scallops 37 (one shown) to expose a cutting edge 38 at the leading edge of the external thread 33, which cutting edge forms female bone threads in the bore upon rotation of the hollow shaft.

Detritus created by tapping instrument 30 is deposited through the scallops 37 into a reservoir provided by a central recess 39 in the pilot rod 34. The end 35 of the pilot rod which extends from the recess 39 into the bore has external threads which, when the threaded pilot rod 34 is turned, carry detritus upwardly to be deposited through the scallops into the reservoir.

Upon rotating the hollow shaft 31 to form female bone threads in the bore, the surgeon can feel increased back pressure when the reservoir becomes full and should grasp the knurled cap 35A to remove and clean out the pilot rod. If the gummy nature of the detritus were to prevent the pilot rod from being easily pulled out of the hollow shaft, the knurled cap 35A could be removed to permit the hollow shaft 31 to be unscrewed from the threaded bore, leaving the pilot rod in place. The pilot rod then serves as a guide if the bore has not yet been completely tapped and it is necessary to reinsert the hollow shaft to complete the tapping.

The wrench 40 of Fig. 4 has a cylindrical shaft 41 with a T-handle 42 at one end and an octagonal protuberance 44 at the other end. The corners of the protuberance 44 fit into recesses in the fusion basket to permit the fusion basket to be rotated by rotating the wrench. A spring-loaded ball 46 frictionally holds the protuberance in place when it is inserted into the fusion basket.

Implanting the Fusion Basket

In order to implant the novel fusion basket between adjacent vertebrae, soft, collagenous disc material is first removed from the intervertebral space. A small window is created in the overlying laminae of each side, namely, standard laminotomies. The neural tissues, dural sac and nerves, are retracted medially. The intervertebral space is cleaned of disc material in a standard surgical fashion. If the disc space has narrowed as a result

of degeneration, a scissors-jack type vertebral spreader or a hydraulically inflated bladder is inserted on one (the first) side inside the disc space and opened until the space approximates the normal. This may be confirmed by a lateral x ray. The height of the disc space is measured on the x ray so that the proper sizes of drills, tap, and fusion basket may be chosen.

The opposite (second) side of the same disc space is then addressed. The nerve tissues on the first side are relaxed and then retracted medialward on the second side. A pilot drill (e.g., 5 mm or 8 mm diameter depending upon discal space height) cuts a small channel in the face of each of the vertebrae, penetrating the interdiscal space to a depth of about mm (the normal disc space is about 30 mm deep and 50 mm wide). A drill stop may be applied to the drill to prevent overboring the hole. A solid rod pilot is then inserted into the pilot hole and a pilot cutter (7 mm or 10 mm) is passed over it and brought downward to enlarge the pilot channels to slidably receive the pilot rod 35 of the tapping instrument 30 of Fig. 3. The cutting thread 33 (12 mm or 16 mm major diameter) cuts female bone threads through the opposing vertebral end plates and into both cancellous regions that will invite the ingrowth of new bone.

A V-thread fusion basket of the invention, with one end cap in place, is snapped onto the wrench 40 of Fig. 4 by which it is screwed by hand into the threaded intradiscal bore to its full depth. After removing the wrench, the basket is packed with bone chips or other bone-inducing substance, and the second end cap is applied to hold the bone chips securely in place.

After removing the vertebral spreader, the dura and nerves on the second side are relaxed and attention is once again directed to the first side which is drilled and tapped to receive a second fusion basket by the same procedure.

Over a period of several weeks, the bone from the vertebral bodies will grow through the perforations in the fusion baskets and unite with the bone-inducing substance inside them, creating a solid fusion.

It is believed that the novel fusion baskets will primarily be implanted by a posterior approach to the spine, although an anterior approach may be utilized, especially when applied to the cervical spine.

Example 1

The fusion basket of Fig. 1 has been machined from a cylinder of surgically implantable stainless steel to have the following dimensions:

diameter of starting cylinder 16 mm
length of cylinder 25 mm
diameter of each small hole 11 3 mm
diameter of circle on which holes 11 are centered
11.5 mm
diameter of central hole 11 mm
pitch of V-thread 12 2.5 mm/turn
angle at crown of thread 12 60°
fillet radius in valley of thread 12 0.4 mm
axial width of perforations 13 1.6 mm
circumferential breadth of perfs. 13 2.8 mm
when projected onto interior of a cylinder, % of
area perforated 25%

A V-thread fusion basket identical in appearance to one produced as in Fig. 2 can be made from a hollow cylindrical tube. After machining an external thread, a plurality of rectangular keyways are broached in the inner surface to form perforations through the valley of the thread. A continuous technique for making a novel fusion basket starts with a continuous helical spring made from a triangular rod such as the rod 26 used in Fig. 2, then welding or soldering the inner-facing surface of the spring to a plurality of cylindrical wires, each extending parallel to the axis of the spring.

Claims

1. A fusion cage which is a hollow perforate rigid cylinder that can be surgically inserted into a bore that has been formed in two adjacent bony structures and filled and packed with bone chips, thus inviting ingrowth of live bone, wherein the improvement comprises: the fusion cage (a) has an external, substantially continuous helical V-thread by which it can be screwed into mating female threads formed in the bore and (b) is perforated in the valley between adjacent turns of the thread.

2. A fusion cage as defined in claim 1 wherein the V-thread is continuous and the angle at the crown of the V-thread is no more than 90°, but not less than 45°.

3. A fusion cage as defined in claim 2 wherein the angle at the crown of the V-thread is about 60°.

4. A fusion cage as defined in claim 2 wherein the V-thread has from 3 to 8 turns per cm.

5. A fusion cage as defined in claim 2 wherein the valley of the V-thread has a fillet, the radius of which is from 0.35 to 0.75 mm.

6. A fusion cage as defined in claim 1 wherein, when the surface of the fusion cage is projected onto the inner face of a cylinder, the perforations comprise from 30% to 60% of the projected area.

7. A fusion cage as defined in claim 1, which is fitted with removable perforated end caps.

8. A fusion cage as defined in claim 1, the

major diameter of which is from 12 to 16 mm.

9. A fusion cage as defined in claim 1, made of implantable-grade stainless steel.

10. A fusion cage as defined in claim 1, made of biodegradable material.

11. A fusion cage as defined in claim 1, made of x-ray-transparent material.

12. A fusion cage that is a hollow rigid cylinder that is suitable for insertion during surgery into a bore that has been formed in adjacent bony structures and can contain bone inducing substances, thus inviting ingrowth of live bone, the fusion cage having an external, substantially continuous screw thread by which it can be screwed into mating female threads formed in the bore, and, having openings in the valley between turns of the thread.

13. A fusion cage as claimed in claim 12 having any one or more of the features as defined in claims 2 to 11.

14. A fusion cage as claimed in claim 12 or 13, wherein the screw thread is a V-thread.

15. A fusion cage as claimed in any one of the preceding claims for use in fusing adjacent bony structures.

16. A tapping instrument comprising a hollow cylindrical shaft having a handle at one end and an external thread which is formed at the other end with at least one scallop that exposes a cutting edge, and a pilot rod that slidably fits into said bore, projects beyond said other end of the hollow shaft, and is formed with a central recess that communicates with the scallop in the hollow shaft and provides a reservoir for detritus removed by said cutting edge, thus permitting the detritus to be carried away by removing the pilot rod from the hollow shaft.

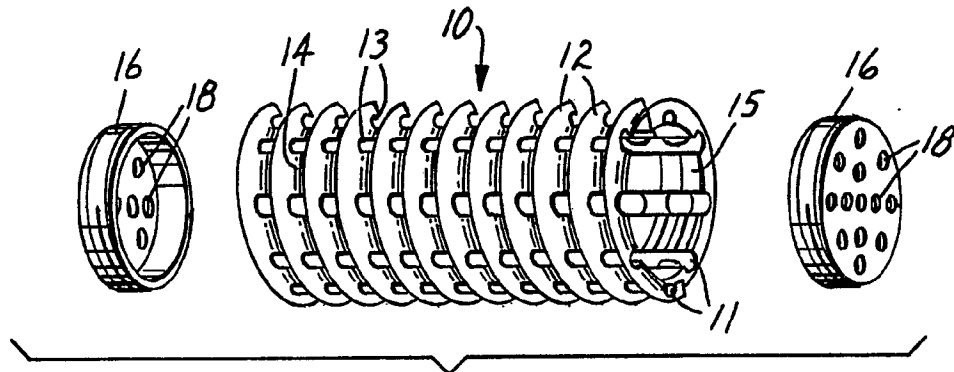


FIG. 1

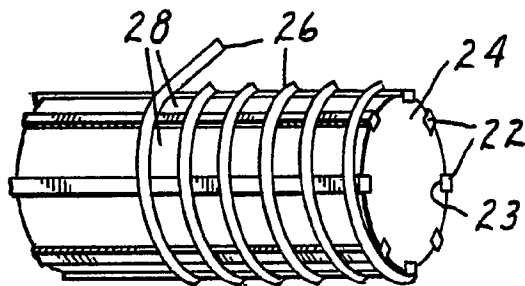


FIG. 2

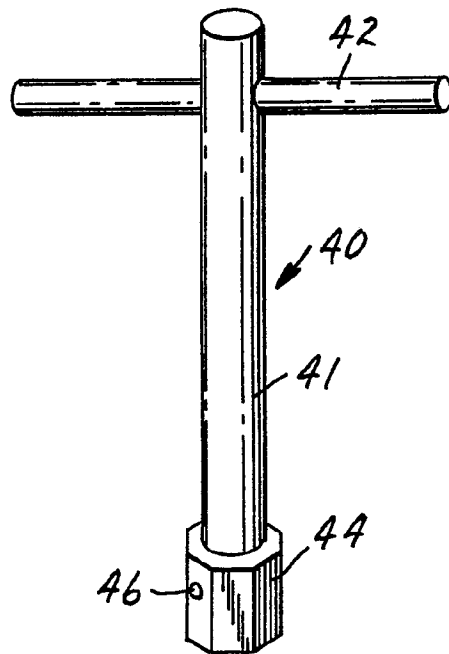


FIG. 4

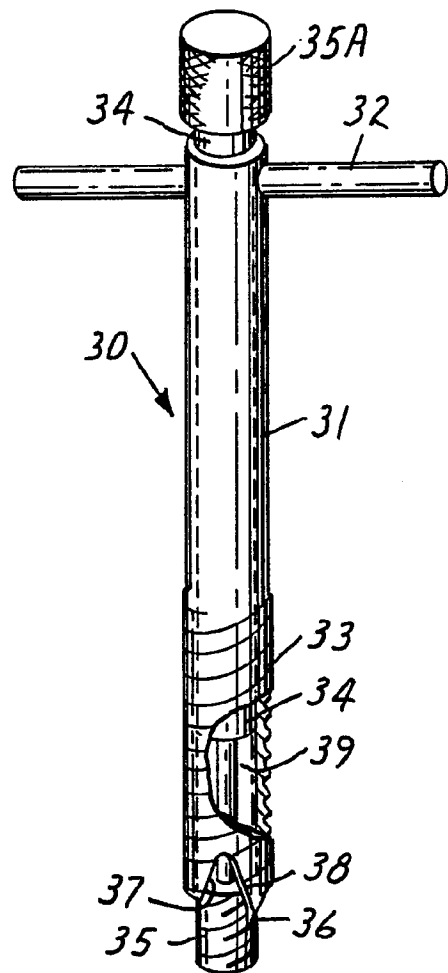


FIG. 3



DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
D,Y	US-A-4 501 269 (BAGBY) * Complete document *	1,7,9, 10,12, 15	A 61 F 2/44
Y	DE-A-3 505 567 (VICH) * Claims; figures *	1,7,9, 10,12, 15	
A		16	
A	WO-A-8 707 827 (S + G IMPLANTS)		
A	EP-A-0 268 115 (BIEDERMANN)		
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A 61 F
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 16-01-1990	Examiner SANCHEZ Y SANCHEZ J.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

Die Erfindung betrifft eine Vorrichtung zum Adaptieren der Länge einer Endoprothese für Röhrenknochen.

Bei bestimmten Indikationen, insbesondere Knochentumor, ist es oftmals notwendig, Röhrenknochen, wie beispielsweise den Femurknochen ganz oder teilweise zu ersetzen. Im Falle eines Totalersatzes wird der erkrankte Knochen entfernt und durch eine Totalendoprothese ersetzt, die im Falle des Femurknochens zwei Endoprothesegelenkteile, nämlich ein Hüftgelenksteil und ein Kniegelenksteil, aufweisen muß.

Eine solche Totalendoprothese ist beispielsweise bekannt geworden aus der DE 31 38 848 A1. Eine darin beschriebene Endoprothese ist zusammengefügt aus zwei Gelenkteilen und Zwischenstücken, wobei die Länge der Zwischenstücke je nach individuellen Patientenerfordernissen im Operationssaal ausgewählt werden kann, so daß die Länge der Endoprothese der Länge des zu entfernenden Knochens angepaßt werden kann.

Mit dieser Endoprothese sind postoperative Längenveränderungen, insbesondere bei noch im Wachstum befindlichen Patienten, nicht möglich. Lediglich ein erneuter schwerer Eingriff würde es gestatten, die einmal implantierte Endoprothese auszutauschen durch eine längere. Dies ist aus medizinischer Sicht nicht vertretbar.

Eine sogenannte Einrichtung zur Wiederherstellung der Extremitätenfunktion ist aus der G 81 08 959.7 UI bekannt geworden. Diese Vorrichtung weist ein künstliches Kniegelenk sowie ein künstliches Hüftgelenk auf, von denen jedes mit jeweils einem von zwei teleskopisch miteinander verbundenen hülsenförmigen Teilen verbunden ist. Die hülsenförmigen Teile sind mittels einer Gewindespindel und einer an einem hülsenförmigen Teil fest angebrachten Gewindehülse durch Drehen der Gewindespindel gegeneinander längs verschieblich, die Vorrichtung also in ihrer Länge einstellbar. Die Vorrichtung kann während der Operation einmal in ihrer Länge eingestellt werden. Ein postoperatives Adaptieren der Länge der Vorrichtung ist nicht vorgesehen und nicht möglich, da keinerlei Einrichtung vorhanden ist, um nach der Implantation die beiden hülsenförmigen Teile zu verschieben.

Aus der DE 33 36 004 C1 ist ein Adapter für eine Knochen-Endoprothese bekannt geworden, der zwischen einem Gelenkteil und einem Prothesenschaftteil angeordnet ist. Dieser Adapter ist getriebeartig aufgebaut derart, daß auf Betätigung eines Schraubenkopfes die hülsenartigen Adapterteile auseinander oder zueinander bewegt werden können. Hierbei ist bei einer Längen Anpassung beispielsweise in der Wachstumsphase des Patienten kein Totalersatz der kürzeren Endoprothese nötig, sondern lediglich ein Schnitt vom Operateur auszuführen, um den besagten Schraubenkopf freizule-

gen und zu verdrehen, um den Adapter in seiner Länge den Gegebenheiten anzupassen.

Wenn diese Adapter auch schon Vorteile gegenüber dem modular aufgebauten Endoprothesen gemäß der weiter oben erwähnten Druckschriften aufweisen, so bleibt festzuhalten, daß zur Durchführung der Längen Anpassung noch ein invasiver Eingriff vorgenommen werden muß, nämlich um das Getriebe des Adapters erreichen zu können. Dies wird als nachteilig empfunden, insbesondere im Hinblick auf eine mögliche Keimverschleppung, die im Falle des Ausbruchs einer Entzündung den Erfolg der Implantation der Endoprothese in Frage stellen kann.

Die aus der EP 0290767 A1 bekannt gewordene Endoprothese ist mit einem ganz ähnlichen Problem behaftet. Auch hier sind zwei teleskopisch ineinander fuhrbare Hülsen vorgesehen, die mit weiteren Endoprothesenteilen wie Gelenkteil und Schaftteil verbindbar sind. Eine Hülse ist mit einem Außengewinde, die andere mit einem Innengewinde versehen. Die Längsverstellung der Endoprothese erfolgt über ein Verdrehen der Teile, wobei ein Kegelradgetriebe vorgesehen ist, dessen Antriebswispindel postoperativ von außen durch eine Stichinzision zugänglich gemacht werden kann.

Schließlich sei auf die noch weiter fern liegende Vorrichtung gemäß der US PS 4863473 hingewiesen, mit Hilfe derer das Skelett eines Verstorbenen nach Entnahme von Knochenteilen zu Transplantationszwecken optisch wieder hergerichtet werden kann.

Aufgabe der vorliegenden Erfindung ist es daher, eine Vorrichtung zum Adaptieren der Länge einer Endoprothese für Röhrenknochen anzugeben, mit der - bei gegebener Möglichkeit der Anpassung der Länge der Endoprothese vor der Implantation an die zu diesem Zeitpunkt herrschenden Verhältnisse - eine später vorzunehmende Längen Anpassung ohne invasiven Eingriff möglich ist.

Gelöst wird diese Aufgabe durch die Vorrichtung mit den Merkmalen gemäß dem Anspruch 1. Weitere vorteilhafte Ausgestaltungen ergeben sich aus den Unteransprüchen. Die erfindungsgemäße Vorrichtung besteht aus dem eigentlichen Adapter und einer Implantierbaren Pumpe, die ein Flüssigkeitsreservoir aufweist oder mit einem solchen verbunden ist. Der Adapter besteht im wesentlichen aus zwei ineinander längsverschieblich gelagerten, kopfseitig jeweils geschlossenen Hülsen. Diese Hülsen schließen gemeinsam in ihrem Inneren einen flüssigkeitsdichten und -befüllten Druckraum ein, der mit der Pumpe über eine Druckleitung in Verbindung steht. Der Druckraum ist dadurch gebildet, daß eine der beiden Hülsen in ihrem Inneren mit einem Kolben versehen ist, der in das Innere der anderen Hülse ragt und dort längsverschieblich bewegbar ist. Er ist zwischen dem inneren Kopfen-

de der anderen Hülse und dem Kolbenkopf begrenzt. Der Druckraum wird gegenüber der Umgebung vorzugsweise durch einen Kolbenring aus körperverträglichem Silikon im Kopfbereich des Kolbens abgedichtet.

Die Vorrichtung bildet also ein entlüftetes, geschlossenes hydraulisches System. Geschlossene hydraulische Systeme sind in der Implantattechnik beispielsweise bekannt geworden aus der DE 37 22 935 AI, DE 38 27 967 AI und DE 38 36 787 AI, die allerdings sämtlich hydraulische Penisprothesen betreffen und auf die daher nur pauschal hingewiesen werden soll.

Der erfindungsgemäße Adapter ist - im Falle der Implantation einer Totalendoprothese für einen Röhrenknochen - zwischen zwei Endoprothesengelenkteilen angeordnet, die über Aufnahmevorrichtungen jeweils an den Kopfenden der beiden Hülsen des Adapters mit diesem verbunden sind. Wenn nur ein Gelenkteil zu resizieren ist und noch ein Rest des Röhrenknochens als Anker für ein Endoprothesen-Schaftteil bleibt, ist der Adapter mit einem Gelenkteil und einem Schaftteil verbunden. Schließlich kann der Adapter zwischen zwei Schaftteilen der Endoprothese angeordnet sein, wenn es gilt, nur ein erkranktes, zu resizierendes Zwischenstück des Knochens zu überbrücken.

Die Pumpe mit dem Flüssigkeitsreservoir wird an geeigneter Stelle, von der sie nach der Implantation von außen durch ein Drücken betätigt werden kann, implantiert.

Die erwähnten Aufnahmevorrichtungen an den Kopfenden der beiden Hülsen für die mit dem Adapter zu verbindenden Endoprothesenteile können in bekannter Weise konisch zulaufende Bohrungen sein, in die entsprechend konisch ausgebildete Zapfen in einen Klemmsitz gebracht werden können.

Als Druckflüssigkeit kommt vorzugsweise eine sterile isotonische Kochsalzlösung zur Anwendung. Selbst im Falle einer Leckage des Systems kommt es dann nicht zu Biounverträglichkeiten.

Eine besonders bevorzugte Ausführungsform des Adapters der erfindungsgemäßen Vorrichtung ist gegenüber den Auswirkungen einer Leckage des Systems und damit gegenüber einer unkontrollierbaren Kontraktion gesichert. Diese Ausführungsform sieht vor, daß die Außenwandung der inneren Hülse des Adapters mit mindestens einer Zahnleiste versehen ist, welche Zähne aufweist, deren ansteigende Zahnflanken in Richtung auf die zulässige Expansionsrichtung des Adapters geneigt sind.

Vorteilhaft ist hier ein Winkel zwischen diesen Zahnflanken und der Expansionsrichtung von ca. 30°. Die abfallenden Zahnflanken hingegen schließen mit der Expansionsrichtung einen Winkel von <90° ein.

Das Gegenstück zu einer solchen Zahnleiste befindet sich innerhalb mindestens einer Ausnehmung im Inneren der äußeren Hülse in Form einer Arretierungsbacke. Diese ist in der Ausnehmung unter Vorspannung in Richtung auf die innere Hülse des Adapters beweglich gelagert. Sie ist an ihre der inneren Hülse zugewandten Seite mit einer Zahnleiste versehen, die entsprechend der Zahnleiste an der Außenwandung der inneren Hülse ausgebildet, zu dieser allerdings umgekehrt angeordnet ist. Die Zahnleisten auf der inneren Hülse des Adapters und jene auf der Arretierungsbacke sind also miteinander verrastbar. Sie sind miteinander verrastet, wenn der Druckraum im Adapter drucklos ist. Dies ist dann der Fall, wenn auf die Betätigung der Pumpe hin eine Ausgleichsbewegung im Sinne einer Expansionsbewegung des Adapters beendet ist. Dies ist aber auch dann der Fall, wenn das System leckt. Der Adapter behält in diesem Fall also die zuletzt eingestellte Lage der Endoprothese bei, dadurch, daß die erwähnten Zahnleisten in fester Verrastung verharren.

Gleichwohl ist bei intaktem System aufgrund der Formgebung der Zahnleisten und unter Aufhebung der Vorspannung, mit der die Arretierungsbacke gegen die innere Hülse gedrückt wird, möglich.

Wird nämlich die Pumpe des Systems betätigt, also der Druckraum druckbeaufschlagt, bewirkt die Form der Zähne der Zahnleisten ein leichtes Abheben voneinander entgegen der besagten Vorspannung, so daß die Arretierungsbacke etwas in Richtung auf das Innere der sie lagernden Ausnehmung gedrückt wird. Ist der Druck im Druckraum groß genug, führt die äußere Hülse eine Ausgleichsbewegung in Expansionsrichtung aus, solange bis der Druck abgebaut ist, worauf die Zahnleisten wieder sofort in die sichere Verrastung übergehen.

Der Adapter weist in besonders bevorzugter Ausbildung an seiner inneren Hülse zwei gegenüberliegende Zahnleisten auf, die mit den Zahnleisten zweier Arretierungsbacken, welche in entsprechend zwei gegenüber liegenden Ausnehmungen in der äußeren Hülse gelagert sind, im beschriebenen Sinne zusammenwirken. Dieser Adapter ist von relativ einfachem mechanischen Aufbau, weist aber sämtliche beschriebenen Vorteile auf.

Die erwähnte Vorspannung der Arretierungsbacken in Richtung auf die innere Hülse des Adapters wird vorzugsweise von Puffern erzeugt, die aus körperverträglichem Silikon bestehen und zwischen den Arretierungsbacken und dem Boden der sie jeweils lagernden Ausnehmungen eingelassen sind.

Für die Voreinstellung der Länge des Adapters bzw. der ganzen Endoprothese vor der Implantation ist es zweckmäßig, die Arretierungsbacken mit einer Vorrichtung zu versehen, die ein zwangsweises Trennen der Zahnleisten voneinander ermöglicht.

Hierbei sind die Arretierungsbacken vorzugsweise jeweils mit einer von außen zugänglichen Gewindebohrung versehen, in die eine Gewindeschraube geschraubt werden kann, um die Arretierungsbacken gegen den Boden der sie lagernden Ausnehmungen zu ziehen, wobei die Zahnleisten außer Eingriff kommen. Nach erfolgter Voreinstellung der Länge werden die Gewindeschrauben entfernt, so daß die erwähnte Verrastung der Zahnleisten eintritt.

Das generelle Prinzip der Verrastung gegeneinander beweglicher Teile eines Implantates ist im übrigen beschrieben in der nachveröffentlichten DE 4012622 C1, die allerdings ein rein mechanisches Wirbelkörperimplantat beschreibt.

Die erfindungsgemäße Vorrichtung gestattet - wie eingangs erwähnt - eine postoperative Längenverstellung im Sinne einer Expansion der mit ihrem Adapter verbundenen Endoprothese ohne invasiven Eingriff. Sie wird anhand eines Ausführungsbeispiels gemäß den Zeichnungen näher erläutert. Es zeigt:

- Fig. 1 eine Schnittansicht des prinzipiellen Aufbaus der erfindungsgemäßen Vorrichtung,
- Fig. 2 eine geteilte Schnittansicht durch den Adapter auf der Höhe A bzw. B gemäß Fig. 1, und
- Fig. 3 eine vergrößerte Ansicht der Einzelheit Z aus Fig. 1.

In den Figuren sind gleiche Teile mit denselben Bezugszeichen versehen.

Die Vorrichtung besteht aus dem Adapter 1 und der mit ihm über eine Druckleitung 10 in Verbindung stehenden manuell betätigbaren Pumpe 9, die aus einem Flüssigkeitsreservoir 8 Flüssigkeit in den Adapter 1 pumpen kann. Die Pumpe 9 besteht ebenso wie das Flüssigkeitsreservoir 8 aus körpervertäglichem Silikon. Auch die Druckleitung 10 besteht - wie im übrigen auch die Versorgungsleitung zwischen dem Flüssigkeitsreservoir 8 und der Pumpe 9 - aus bioverträglichem Silikon.

Der Adapter 1 ist zwischen zwei Endoprothesenteilen anzuordnen, von denen in Fig. 1 zur Veranschaulichung ein Gelenkteil 21 für ein Kniegelenk dargestellt ist, das die natürlich Kondylen des Femurteils des Gelenks durch Gleitkufen nachbildet.

Der Adapter 1 besteht aus zwei ineinander verschieblich gelagerten, kopfseitig geschlossenen Hülse 3 und 4. Diese weisen in ihrem äußeren Kopfende jeweils eine konisch sich verjüngende Bohrung 5 bzw. 6 auf, in der die Endoprothesenteile mit entsprechend ausgebildeten Zapfen in einen Klemmsitz gebracht werden können. Dies ist für das Gelenkteil 21 in Fig. 1 angedeutet.

Die äußere Hülse 3 ist mit einem Kolben 11 versehen, der paßgenau in das Innere der inneren

Hülse 4 ragt. Der Kolben 11 ist mit der Hülse 3 längsverschieblich in der Hülse 4 bewegbar.

Zwischen dem Kopf des Kolbens 11 und dem inneren Kopfende der Hülse 4 ist ein Druckraum 7 begrenzt, der über einen nicht dargestellten Anschlußstutzen mit der Druckleitung 10 verbunden ist. Der Druckraum 7 ist durch den Kolbenring 20, der im Kopfbereich des Kolbens 11 in diesen eingelassen ist, abgedichtet.

Das Flüssigkeitsreservoir 8, die Anschlußleitung zur Pumpe 9, die Pumpe 9 selbst, die Druckleitung 10 und schließlich der Druckraum 7 sind mit Flüssigkeit gefüllt und bilden ein entlüftetes, geschlossenes hydraulisches System. Wird der Druckraum 7 durch Betätigung der Pumpe 9 druckbeaufschlagt, so führt die Hülse 3 eine Ausgleichsbewegung in die Expansionsrichtung X aus.

Der Kopfteil der Hülse 4 ist vorliegend im übrigen derart an das spezielle Gelenkteil 21 angepaßt, daß es je eine Halterung 22 bzw. 23 für das Flüssigkeitsreservoir 8 bzw. für die Pumpe 9 aufweist. So ergibt sich eine kompakte implantierbare Einheit.

Wie aus den Fig. 1 und 2 deutlich zu erkennen ist, sind an der Außenwandung der inneren Hülse 4 zwei Zahnleisten 12 und 13 vorgesehen. Deren Zähne 14 sind, wie anhand Fig. 3 deutlich wird, so ausgebildet, daß die ansteigenden Zahnflanken in Richtung X der Expansionsbewegung geneigt sind, und zwar in einem Winkel α von ca. 30° . Die abfallenden Zahnflanken schließen einen Winkel β zur Richtung X ein, der $< 90^\circ$ sein muß.

Im Inneren der äußeren Hülse 3 sind zwei Ausnehmungen 15, 16 vorgesehen. In diesen ist jeweils eine Arretierungsbacke 18 bzw. 17 gelagert. Deren zur inneren Hülse 4 gewandte Stirnflächen weisen jeweils eine Zahnleiste auf, die entsprechend den Zahnleisten 13 und 14 an der inneren Hülse 3 ausgebildet, aber umgekehrt zu diesen angeordnet sind.

Im Boden jeder Ausnehmung 15 und 16 sind jeweils Puffer 19 aus Silikon eingelassen, welche die Arretierungsbacken 17 und 18 in Richtung auf die innere Hülse 3 drücken. Die Anordnung ist derart, daß die Ausnehmungen 15 und 16 mit den darin gelagerten Arretierungsbacken 18 bzw. 17 jeweils gegenüber einer Zahnleiste 12 bzw. 13 an der Außenwandung der inneren Hülse 3 liegen.

Wenn der Druckraum 7 drucklos ist, also auch keine der durch die Puffer 19 erzeugte Vorspannung der Arretierungsbacken 17 und 18 entgegengesetzte Kraft wirkt, sind die Zahnleisten der inneren Hülse 3 und jene der Arretierungsbacken in sicherer, aber lösbarer Verrastung. Diese bietet u.a. Sicherheit gegen eine unkontrollierte Kontraktion des Adapters 1 im Falle einer Leckage des hydraulischen Systems. Die Sicherheit bestimmt im übrigen entscheidend der bereits erwähnte Winkel β

der abfallenden Zahnflanken mit. Wären auch Werte für β von $> 90^\circ$ zugelassen, könnte es zu einem Abrutschen der äußeren Hülse 3 kommen, wenn Belastungskräfte entgegen der Richtung X wirken. Aufgrund der Vorgabe aber, daß $\beta < 90^\circ$ sein muß, ist dies nicht möglich.

Dennoch ist trotz des innigen Eingriffs der Zahnleisten eine Expansion des Adapters möglich. Wird nämlich der Druck im Druckraum 7 erhöht durch Betätigen der Pumpe 9, wird eine die Vorspannung der Arretierungsbacken 17 und 18 teilweise aufhebende Kraft erzeugt, so daß die Verrastung der Zahnleisten teilweise aufgehoben wird. Die Ausgleichsbewegung der Hülse 3 in die Richtung X bewirkt eine Bewegung der Zahnleisten gegeneinander gewissermaßen Zahn um Zahn. Nach dem Druckabbau im Druckraum 7 kehrt das System automatisch in die sichere Verrastungsstellung zurück. Entscheidend für die Möglichkeit der Ausführung einer Bewegung in Richtung X der Expansion trotz inniger Verrastung der Zahnleisten im Ruhezustand des Adapters 1 ist die Wahl des Winkels α der ansteigenden Zahnflanken. Als vorteilhaft hat sich ein Wert für α von ca. 30° ergeben.

Jede der Arretierungsbacken 17 und 18 weist im übrigen eine Gewindebohrung 24 auf, in die durch eine Bohrung in der äußeren Hülse 3 eine Gewindeschraube (nicht dargestellt) geschraubt werden kann. Die Schraube soll so ausgebildet sein, daß sie sich mit ihrem Kopf an der Hülse 3 anlegt, wenn die Arretierungsbacken 17 und 18 unter Aufheben der Vorspannkraft von den Puffern 19 zwangsweise zum Boden der Ausnehmungen 16 bzw. 15 gezogen werden. Die Ausnehmungen 15 und 16 haben eine solche Tiefe, daß die Zahnleisten 12 und 13 und jene der Arretierungsbacken dann völlig außer Eingriff kommen. In dieser Lage kann der Adapter 1 vor der Implantation in seiner Länge voreingestellt werden.

Patentansprüche

1. Vorrichtung zum Adaptieren der Länge einer Endoprothese für Röhrenknochen, bestehend aus

einem Adapter (1), der zwischen einem mit ihm verbundenen Endoprothesengelenkteil und einem Endoprothesenschaftteil oder zwischen zwei Endoprothesengelenkteilen oder zwischen zwei Endoprothesenschaftteilen anzuordnen ist und aus zwei ineinander verschieblich gelagerten, kopfseitig geschlossenen Hülsen (3, 4) aufgebaut ist, die an ihrem jeweiligen äußeren Kopfende eine Aufnahmevorrichtung (5, 6) für die mit dem Adapter (1) verbundenen Endoprothesenteile aufweisen und von denen eine

in ihrem Inneren einen Kolben (11) aufweist, der in dem Inneren der anderen Hülse (4) längsverschieblich bewegbar ist und zusammen mit dem inneren Kopfende der anderen Hülse (4) einen flüssigkeitsdichten und flüssigkeitsbefüllten Druckraum (7) einschließt, und aus

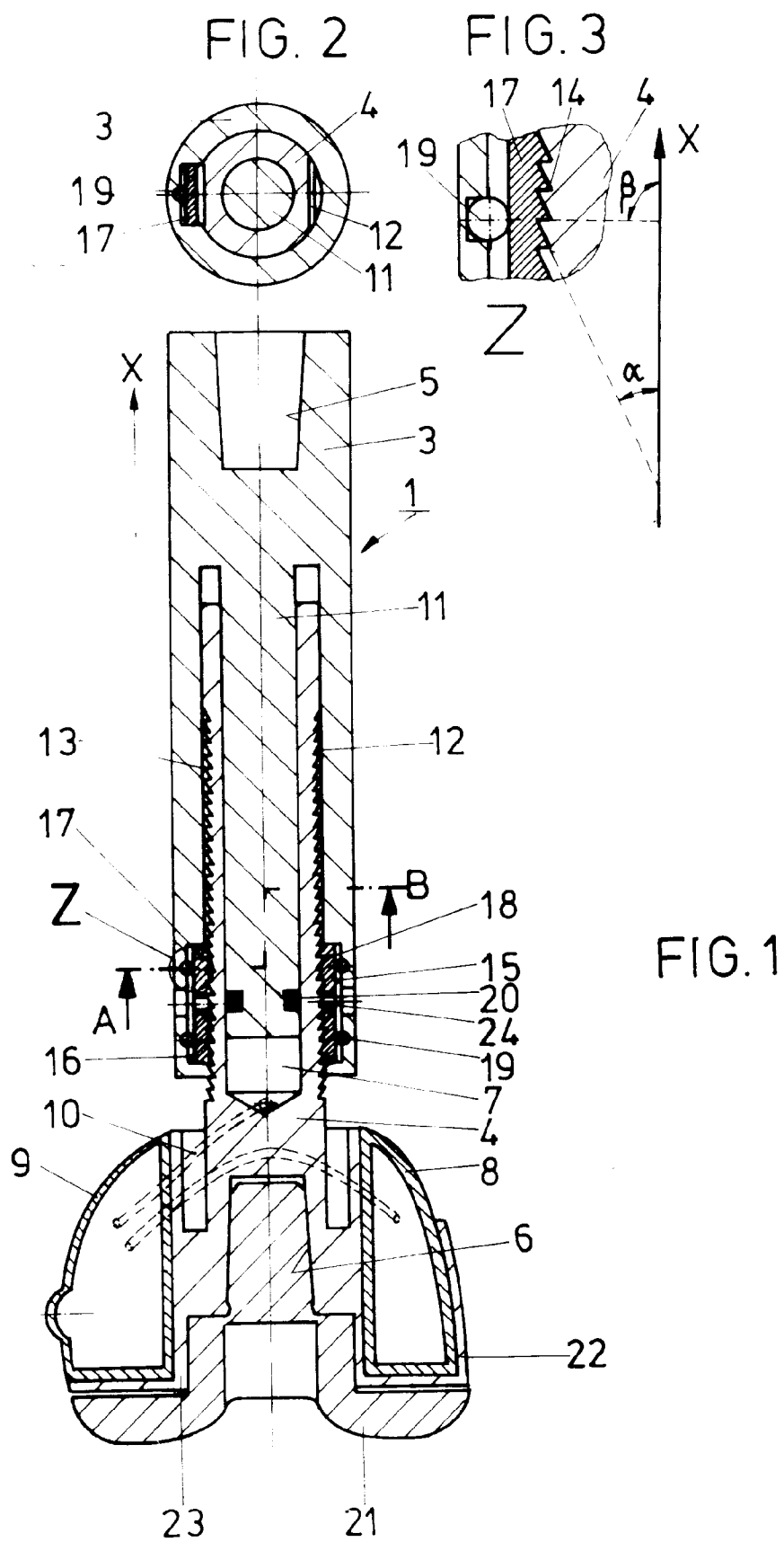
einer ein Flüssigkeitsreservoir (8) aufweisenden, aus körpervertäglichem Material bestehenden Pumpe (9), die mit dem Druckraum (7) über eine Druckleitung (10) in Verbindung steht, durch welche unter Pumpwirkung Flüssigkeit in den Druckraum (7) einleitbar ist.

2. Vorrichtung nach Anspruch 1, bei der die Außenwandung der inneren Hülse (4) des Adapters (1) mit mindestens einer Zahnleiste (12, 13) mit Zähnen (14) versehen ist, deren ansteigende Zahnflanken in Richtung X der zulässigen Expansionsbewegung des Adapters geneigt sind und deren abfallende Zahnflanken einen Winkel von kleiner 90° zur Richtung X der Expansionsbewegung einschließen, und bei der im Inneren der äußeren Hülse (3) mindestens eine Ausnehmung (15, 16) vorgesehen ist, innerhalb der eine Arretierungsbacke (17, 18) unter Vorspannung in Richtung auf die innere Hülse (4) beweglich gelagert ist, die eine entsprechend der Zahnleiste (13, 14) der inneren Hülse (4) ausgebildete und komplementär zu dieser angeordnete Zahnleiste aufweist, welche in drucklosem Zustand des Druckraums (4) mit jener verrastet ist, derart, daß eine Bewegung der äußeren Hülse (3) entgegen der Expansionsbewegung unmöglich ist, wobei der Eingriff der Zahnleisten bei Druckbeaufschlagung des Druckraumes (7) soweit entgegen der erwähnten Vorspannung aufgehoben wird, daß eine Bewegung der äußeren Hülse (3) in Expansionsrichtung X ermöglicht wird.

3. Vorrichtung nach Anspruch 2, bei der die Vorspannung der Arretierungsbacke (17, 18) von mindestens einem zwischen ihr und der Innenwandung der Ausnehmung (15, 16) angeordneten flexiblen Silikonpuffer (19) erzeugt wird.

4. Vorrichtung nach Anspruch 2 oder 3, bei der die innere Hülse (4) zwei gegenüberliegende Zahnleisten (12, 13) aufweist, die in drucklosem Zustand des Druckraumes (7) mit den Zahnleisten zweier Arretierungsbacken (17, 18), die in entsprechend zwei gegenüberliegenden Ausnehmungen (15, 16) in der äußeren Hülse (3) gelagert sind, verrastet sind.

5. Vorrichtung nach einem der Ansprüche 2 bis 4, bei der die Arretierungsbacke (17, 18) mit einer von außen zugänglichen Gewindebohrung (21) versehen ist, in die eine Gewindeschraube schraubbar ist, um die Zahnleiste der Arretierungsbacke (17, 18) zwangsweise entgegen der Richtung der Vorspannung außer Eingriff aus der Zahnleiste (12, 13) an der inneren Hülse (4) zu bringen. 5
- 10
6. Vorrichtung nach einem der Ansprüche 1 bis 5, bei der der Druckraum (7) gegenüber der Umgebung durch einen Kolbenring (20), der im Kopfbereich des Kolbens (11) angebracht ist, aus körperverträglichem Silikon abgedichtet ist. 15
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Kategorie	Kennzeichnung des Dokuments mit Angabe, soweit erforderlich, der maßgeblichen Teile	Betrifft Anspruch	KLASSIFIKATION DER ANMELDUNG (Int. Cl.5)
X	FR-A-2 267 080 (MESSERSCHMITT) * Seite 2, Zeile 23 - Zeile 30; Abbildungen *	1	A61F2/30
A	GB-A-2 039 220 (WEVERS) * Seite 3, Zeile 96 - Zeile 104; Abbildungen *	2	
A	GB-A-2 137 884 (SCALES)	-	
D,A	EP-A-0 290 767 (HOWMEDICA)	-	
			RECHERCHIERTE SACHGEBIETE (Int. Cl.5)
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(54) **Wirbelkörperimplantat.**

(57) Als Implantat für Wirbelsäulen wird eine Scheibe (11) vorgeschlagen, die alleine oder zu mehreren gestapelt (11 bis 14) zwischen Wirbelkörper einsetzbar sind. Einzelne Scheiben werden nach Bedarf von einem Strang abgeschnitten, wobei die Scheibendicke dem Einzelfall genau angepaßt werden kann. Diese Implantate eignen sich insbesondere für Halswirbel sowie als Ersatz nach der Entfernung von Bandscheiben. Für die Bildung eines Implantats aus mehreren übereinandergestapelten Scheiben kann ein entsprechendes Sortiment von Scheiben bereitgestellt werden, die sich sowohl im Durchmesser als auch in der Höhe unterscheiden. Für den jeweiligen Anwendungszweck werden demzufolge Scheiben mit entsprechender Dicke ausgesucht und zusammengesetzt, so daß sie insgesamt die erforderliche Höhe des Implantats ergeben. Verschraubungen und insbesondere längere Handhabungen im eingesetzten Zustand des Implantats sind bei dem erfindungsgemäßen Implantat nicht erforderlich.

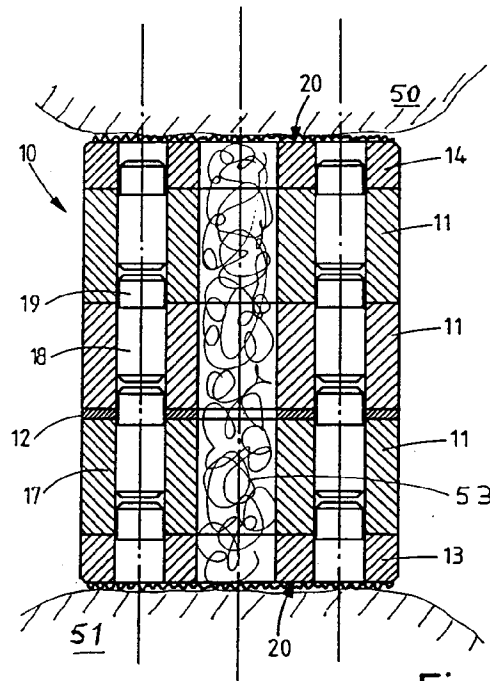


Fig.1

EP 0 517 030 A2

Die Erfindung bezieht sich auf ein Implantat für Wirbelsäulen, bestehend aus mindestens einem steifen Element.

Wirbelkörper haben entlang einer Wirbelsäule unterschiedliche Größen und sind von Patient zu Patient auch unterschiedlich. Beim Ersetzen eines Wirbelkörpers durch ein Implantat ist es daher notwendig, das Implantat an die effektive Dimension des Abstandes zwischen den angrenzenden Wirbelkörpern anzupassen.

Umdiesen Umstand Rechnung zu tragen, wurden die Implantate entwickelt (DE 30 23 942 C3), die aus im wesentlichen zwei in Schraubenverbindung stehenden Teilen bestehen, und deren axiale Höhe durch Drehen verändert bzw. an den Abstand zwischen den Wirbelkörpern angepaßt werden kann. Mittels Querschrauben oder anderen Verankerungsmitteln werden die beiden Teile nach ihrer Einstellung dreh sicher verankert. Damit läßt sich zwar mittels einer Ausführung eine ganze Bandbreite von Abständen abdecken, aber die Höheneinstellung nimmt jedoch insbesondere bei einem feinen Gewinde relativ viel Zeit in Anspruch.

Diesen Nachteil behebend, ist aus der WO 90/00037 ein Implantat der gattungsgemäßen Art bekanntgeworden, das mittels eines Werkzeugs lediglich zwischen zwei Wirbel eingeschoben wird. Das annähernd quaderförmige Implantat wird jedoch aus komplizierten Einzelteilen zusammengesetzt.

Der Erfindung liegt daher die Aufgabe zugrunde, ein Implantat der eingangs genannten Art zu entwickeln, das rasch implantierbar ist, aber auch fertigungstechnisch einfach für eine Vielfalt von Abmessungen hergestellt werden kann.

Die Aufgabe wird erfindungsgemäß mit den Merkmalen des Anspruches 1 gelöst.

Eine Scheibe ist nicht nur sehr einfach in einen Wirbelspalt einzusetzen, sondern auch sehr leicht und dimensionsmäßig auf den Anwendungsfall angepaßt herstellbar. So ist es beispielsweise möglich, die Scheibe erst bei einer spezifischen Anwendung aus einem vorgefertigten vollen oder hohlen Strang herauszuschneiden, zu sterilisieren oder im sterilen Zustand mit einem sterilen Schleifwerkzeug und sterilem Wasser zu trennen und einzusetzen. Durch Verwendung eines grobkörnigen Schleif- bzw. Schneidwerkzeuges erhalten die Schnittflächen der Implantatscheibe, die die Auflagen für die Wirbelkörper bilden, eine den Anwuchsprozeß fördernde raue Oberfläche.

Im Prinzip ist die Verwendung einer Scheibe jeder Konfiguration, rund, mehreckig, unregelmäßige Kontur möglich. Auch die innere Kontur einer ringförmigen Scheibe kann nach Bedarf gestaltet werden.

Die für den angrenzenden Wirbelkörper dienende Auflagefläche einer Scheibe ist zur Förde-

rung des Anwuchsprozesses strukturiert, rau oder in unterschiedliche Richtungen gewählt ausgebildet. Verankerungsmittel in der Form von herausragenden Spitzen dienen der sofortigen Sicherung der Prothese nach der Implantation.

Das scheiben förmige Implantat wird vorzugsweise aus faserverstärktem Kunststoff hergestellt. Für ein einteiliges Implantat wird gemäß einer bevorzugten Ausgestaltung der Erfindung die Scheibe aus einem hohlen Strang herausgeschnitten, der aus einer Vielzahl von Flechtlagen besteht. Die Flechtlagen werden nacheinander auf einen entsprechend geformten Dorn, vorzugsweise auf einen Dorn mit rechteckigem Querschnitt und abgerundeten Ecken direkt in einer Flechtmaschine aufgezogen. Die Scheiben werden mit der gewünschten Höhe, die über die Scheibe variieren kann, abgeschnitten. Derartige Implantate zeichnen sich durch ihre außerordentlich leichte Herstellbarkeit aus, bei der die Faserorientierungen gleich eine optimale Steifigkeit und Festigkeit des Implantats bewirken.

Gemäß einer weiteren Ausgestaltung der Erfindung werden zur Bildung eines Wirbelkörperimplantats zwei oder mehrere Scheiben zusammengesetzt. In diesem Fall wird ein Vorrat von einem Sortiment von Scheiben unterschiedlicher Höhe und Durchmesser gehalten. Für eine Implantation wird der Abstand zwischen den Wirbeln gemessen und entsprechend dicke bzw. hohe Scheiben aus dem Sortiment zusammen kombiniert, derart, daß sie in ihrer Gesamtheit die gewünschte Höhenabmessung haben. Die herausgesuchten Scheiben, sie bestehen aus Teilen gleicher Form, nur mit unterschiedlicher Höhe, werden im Baukastenprinzip aufein andergestapelt und als fertiges Implantat zwischen die Wirbelkörper gesetzt, die dazu geringfügig auseinandergezogen werden. Auch hier ist nach dem Einsetzen des Implantats keine Regulierung oder Justierung desselben innerhalb des Patientenkörpers erforderlich.

Mit Hilfe eines Computers lassen sich die zu kombinierenden Höhen der Scheiben sekundenschnell ermitteln, so daß zwischen Wirbelabstandsvermessung bis zum Erhalt des einsetzbaren Implantats ein minimaler Zeitaufwand erforderlich ist. Die radiale und dreh sichere Verankerung der zusammengesetzten Scheiben läßt sich vielfältig bewältigen.

Gemäß einer Ausgestaltung der Erfindung weisen die Scheiben fluchtende Bohrungen auf, in die Verankerungsstifte eingesetzt werden. Bei dieser Ausgestaltung sind die Scheiben sowohl radial als auch dreh sicher miteinander verbunden. Außerdem sind die Scheiben fertigungstechnisch sehr einfach herzustellen.

Eine andere Möglichkeit ist, die Scheiben direkt mit eingeformten Verankerungsmitteln, wie z.B. Nut und Feder, Stift und Bohrung, herzustellen.

Auch die Scheibenpackungen können als Ringscheiben ausgebildet werden, wobei der Hohlraum zur radialen Verankerung der Ringe mit Knochenmaterial oder -zement ausgefüllt werden kann. Vorteilhaft ist es, wenn der Innenmantel der Ringscheiben unregelmäßig ist oder geometrische Unregelmäßigkeiten aufweist. Jede Abweichung von der kreiszylindrischen Form dient zur drehsicheren Verankerung der aufgestapelten Scheiben, wenn der Hohlraum der Ringscheiben mit einem härten-

Für den sicheren Halt des als Scheibenstapel ausgebildeten Implantats zwischen den angrenzenden Wirbelkörpern werden Endscheiben mit einer rauhen Stirnseite vorgesehen. Die Rauigkeit kann durch eine strukturierte Oberfläche, herausragende Spitzen, Wellen und dergleichen erzeugt werden.

In jeder Ausführung ist es möglich, die Scheiben zu einer soliden Einheit miteinander zu verkleben, z.B. mit PMMA-Zement, wenn erforderlich oder zweckmäßig.

Die Scheiben werden vorzugsweise aus einem kohlenstoffaserverstärkten Kunststoff (CFK) hergestellt, wobei die Verankerungsmittel je nach Ausgestaltung des Implantats aus demselben oder einem anderen Material bestehen können. Die Herstellung des gesamten Implantats aus CFK hat den Vorteil, daß das Implantat keine Streuung von Strahlen bewirkt, so daß die Wirbelsäule und das angrenzende biologische Gewebe auch nach dem Implantieren eines Wirbelkörperersatzes mit allen bildgebenden Verfahren (CT, MR) untersucht werden kann.

Bekannte Wickeltechniken lassen sich zur serienmäßigen Fertigung der Implantat-Elemente anwenden. Die Ringscheiben können beispielsweise mittels einer Flechtmaschine, die zusätzlich mit unidirektionalen Fasern (UD) bestückt ist, hergestellt werden. Mittels eines Stabdornes, der durch das Flechtauge gezogen und mit UD-Fasern und Flechtwerk umlegt wird, wird ein Faserverbundrohr in einem Arbeitsgang hergestellt, von dem dann die Ringscheiben abgeschnitten werden. Der Stabdorn ist vorzugsweise aus dem auch als Trennmittel verwendbaren PTFE (Polytetrafluorethylen). Der Stabdorn kann dabei ein Vieleck als Querschnitt haben oder über die Länge Nuten und/oder Erhebungen aufweisen, wodurch im Faserverbundrohr bzw. in den Ringscheiben die für die drehsichere Verankerung erforderliche Innenmantelgeometrie direkt bei deren Herstellung gebildet wird.

Auch Wickelverfahren unter Anwendung von Fasern oder Fasergelegen erlauben fertigungstechnisch einfache und für Serienfertigung geeignete Herstellverfahren. Es können einheitliche Streben für die Einzelscheiben und die Scheibenpackungen konzipiert werden.

Die Erfindung wird anhand von in der Zeich-

nung schematisch dargestellten Ausführungsbeispielen näher erläutert. Es zeigen:

Figuren 1 und 2

ein erstes Ausführungsbeispiel,

Figuren 3 und 4

ein zweites Ausführungsbeispiel,

Figuren 5 bis 8

je ein weiteres Ausführungsbeispiel.

Der Erfindung liegt der Gedanke zugrunde, daß der Chirurg an Ort und Stelle direkt nach Kenntnis der tatsächlichen Abmessungen den Wirbelkörperersatz zusammenstellt, ohne die Hilfe eines Prothesentechnikers. Dazu wird ein Vorrat von Strängen unterschiedlicher Durchmesser und/oder eines Sortiments von Implantatkomponenten unterschiedlicher Durchmesser und Höhen gehalten, so daß für den jeweiligen Fall entweder eine entsprechende dicke Scheibe aus dem entsprechenden Strang herausgetrennt oder die entsprechende Anzahl von Komponenten mit entsprechenden Abmessungen herausgeholt und zusammengesetzt zu werden braucht, ohne Schraubjustier- oder andere Handgriffe vornehmen zu müssen. Die Auswahl der Scheiben nach ihrer Höhe im letzten Fall kann mittels eines Rechners erfolgen.

Die Grundlage eines zusammengesetzten Implantats besteht im Aufstapeln von vorgefertigten Scheiben, wobei diese Scheiben eine runde, mehrckige oder unregelmäßige Außenkontur haben können. Es können volle Scheiben oder auch Ringscheiben als Komponenten verwendet werden. Es werden Scheibensätze mit unterschiedlichen Durchmessern benötigt, wobei jeder Satz eines Durchmessers mit Scheiben unterschiedlicher Höhe bestückt ist. Steht der Durchmesser des einzusetzenden Implantats fest, so werden in dem entsprechenden Scheibensatz noch die entsprechenden Höhen ausgesucht, so daß nach dem Zusammensetzen der gewählten Scheiben sich die erforderliche Implantathöhe ergibt.

Um das Sortiment bezüglich der Scheibenhöhe möglichst klein zu halten, können beispielsweise wenige hohe Abmessungen vorgesehen werden, die mit niedrigen Scheiben, z.B. millimeterdicken Scheiben, entsprechend ergänzt werden.

In Fig. 1 ist ein Ausführungsbeispiel gezeigt, bei dem ein fertiges Implantat 10 aus drei dickeren Scheiben 11, einer dünnen Scheibe 12 und zwei Endscheiben 13 bzw. 14 zusammengesetzt ist.

Wie in Fig. 2 dargestellt ist, bestehen die Scheiben 11 bis 14 aus runden Ringscheiben mit einer Innenbohrung 15 und jeweils vier regelmäßig auf die Ringscheibe verteilten Bohrungen 16. In diese Bohrungen 16 werden Verankerungsstifte 17 eingeführt. Gemäß der Ausführung nach Fig. 1 sind die Stifte 17 mit ihrem jeweils einem Ende 18 mit einer Scheibe 11, 13 verbunden, während sie mit dem anderen Ende 19 in die Bohrung einer näch-

sten Scheibe 11 hineinragen. Bei dieser Ausgestaltung wird eine Endscheibe 14 ohne Stift auszustalten sein. In gleicher Weise werden die dünnen Scheiben 12 lediglich Bohrungen 16 aufweisen.

Es ist natürlich auch möglich, die Stifte 17 als von den Scheiben 11 bis 14 getrennte Bauteile herzustellen, so daß die Stifte erst bei dem Zusammensetzen eines Implantats 10 in die Bohrungen 16 eingeführt werden.

Anstelle von Stiften als Verankerungsmittel können auch Nut- und Federsysteme in jeder möglichen Konfiguration vorgesehen werden.

In Fig. 3 ist ein Ausführungsbeispiel gezeigt, bei dem die Scheiben 21 auf der einen Stirnseite mit einer Ringfeder 22 und auf der anderen Stirnseite mit einer damit fluchtenden Ringnut 23 versehen sind. Um eine Verankerung auch in Torsionsrichtung zu erreichen, können anstelle der Ringfeder 22, wie in Fig. 4 gestrichelt angedeutet, Federsegmente 24 vorgesehen werden, die in entsprechende Nutsegmente der nächsten Scheibe eingreifen.

In den dargestellten Ausführungsbeispielen wurden runde Scheiben mit kreissymmetrisch verteilten Verankerungselementen gezeigt. Es ist selbstverständlich jede asymmetrische Anordnung der Verankerungselemente sowie jede Außenkontur der Scheiben möglich, soweit letztere mit der Kontur der Wirbelkörper im Einklang steht.

Ringscheiben oder volle Scheiben lassen sich fertigungstechnisch einfach aus jedem biokompatiblen Material herstellen, da sie an keine besondere Formgebung gebunden sind. Die Form kann sogar teilweise an das Herstellungsverfahren angepaßt werden. Für die Serienfertigung gut geeignete Herstellungsmethoden sind Wickeln oder Ziehen von Faserverbundrohren, aus denen die Scheiben als Einzelelement oder für die vorstehend beschriebenen Scheibenpackungen herausgesägt, -geschnitten bzw. -getrennt werden. Im Wickelverfahren können nach bekannten Methoden Fasern oder Fasermatten verwendet werden. Im Flechtverfahren wird, wie es in Fig. 5 angedeutet ist, ein entsprechend geformter Stabdorn 30, z.B. mit rechteckigem Querschnitt durch ein Fadenauge 31 durchgezogen und dabei mit Bündeln von längsgerichteten, mit Matrix imprägnierten UD-Fasern 32 sowie mit äußeren Flechtfasern 33 umgeben. Nach dem Aushärten der Matrix werden aus dem so hergestellten Faserverbundrohr Ringscheiben 35 herausgetrennt, wobei der Dorn vor oder nach der Trennung der Ringscheiben entfernt wird. Der als Faserverbundrohr ausgebildete Strang dient sowohl zur Herstellung von Einzelscheiben als auch von Scheiben für ein Scheibenpaket gemäß Fig. 1.

Einzelscheiben 35 werden bei Bedarf keilförmig (Fig. 6, $h_1 > h_2$) herausgetrennt. Im neutralen Bereich 37 können Öffnungen 38 vorgesehen wer-

den, die zum Eingriff von Implantationswerkzeugen und Fixationsmitteln, wie Krampen 39 verwendet werden.

Der Hohlraum 36 kann mit fremdem oder dem patienteneigenen Knochenmaterial oder mit Knochenzement ausgefüllt werden, das ebenfalls durch die Öffnung 38 einführbar ist. Bei zusammengesetzten Scheiben dient der Knochenzement gleichzeitig zur Verankerung der Scheiben in radialer Richtung und aufgrund des nicht kreissymmetrischen Innenquerschnittes 36 auch in Torsionsrichtung. Anstelle des rechteckigen Innenquerschnittes kann jede andere Konfiguration außer der Kreisform zur Sicherung gegen Drehbeweglichkeit zwischen den Scheiben gewählt werden.

Fig. 7 zeigt eine Form mit einem zylindrischen Innenmantel 40, der mit einer Nut 41 und einer Erhebung 42 zur Torsionsverankerung ausgestattet ist.

Bei Bedarf werden die Scheiben oder Ringscheiben einseitig mit einer Klebstoffhülse 44 einschließenden Starterfolie 43 versehen, wie in Fig. 7 gezeigt ist. Wenn zwei Scheiben 45 zur Bildung des Implantats aufeinandergelegt und axial gepreßt werden, platzen die Klebstoffhülsen 44 auf, so daß der Klebstoff sich zwischen den Scheiben 45 verteilt und die Scheiben miteinander verbindet. Die Klebverbindung kann als einzige Verbindung oder ergänzend zu den vorstehend genannten Verankerungsmitteln verwendet werden.

In der Ausführung nach Fig. 7 sind ferner Bohrungen 46 gezeigt, die radial durch die Ringscheibe 45 geführt sind. Sie dienen zur Einführung des Knochenzements oder Knochenmaterials in den Hohlraum 47.

Die Endscheiben 13, 14 eines Implantats 10 haben an ihrem freien, die Auflage für den Wirbelknochen dienenden Stirnende eine rauhe, strukturierte oder mit diskreten Erhebungen versehene Oberfläche 20. Diese sollen in Zusammenwirkung mit den angrenzenden, gegen das Implantat 10 drückenden Wirbelkörpern 50, 51 die Verankerung innerhalb der Wirbelsäule gewährleisten und als Anwachshilfe dienen. Wie vorstehend beschrieben, kann bei Bedarf im implantierten Zustand durch eine nichtgezeigte radiale Bohrung Knochenzement oder -material 53 in die Innenbohrung 15 bis an die angrenzenden Wirbelkörper 50, 51 gedrückt werden. Bei einem Einscheiben-Implantat werden beide Seiten entsprechend ausgestaltet. Eine rauhe Fläche läßt sich durch Verwendung einer grobkörnigen Schneidwerkzeuge direkt im Trennvorgang vom Strang bilden.

Die Implantation eines derartigen Wirbel- und/oder Bandscheibenersatzes bedingt keine systemspezifischen Schwierigkeiten. Wenn der chirurgische Schritt soweit gekommen ist, daß der Abstand zwischen den angrenzenden Wirbelkör-

pern feststellbar ist, wird mittels dieses Wertes im Rechner die Zusammensetzung der Scheibenhöhen für das Implantat errechnet, herausgesucht und zusammengesetzt oder mittels eines genau einstellbaren Werkzeugs die Scheibe vom Strang abgetrennt. Die angrenzenden Wirbelkörper werden etwas auseinandergezogen und das im Baukastensystem zusammengesetzte Implantat bzw. die Scheibe zwischengelegt. Außer dem Plazieren des Implantats sind keine weiteren Handgriffe bezüglich des Implantats notwendig. Außer der Implantathöhe variiert auch der Durchmesser des Implantats. Das Scheiben- und/oder Strangsortiment ist daher auch nach Querschnitten zu bestücken.

In Fig. 8 ist schließlich ein hohler Strang 50 unregelmäßiger Konfiguration gezeigt, der aus 1 bis 20 Flechtwerken 51 gebildet ist. Ein nicht gezeigter Dorn wird entsprechend oft durch das Ringfadenaugen einer Flechtmaschine gezogen und dabei mit entsprechend vielen Flechtwerken und Matrixmaterial überzogen. Mit Trennscheiben werden an Trennlinien 52 die Scheiben 53 für ein Implantat oder Implantatelement herausgeschnitten.

Patentansprüche

1. Implantat für die Wirbelsäule, bestehend aus mindestens einem steifen Element, dadurch gekennzeichnet, daß das Implantat aus mindestens einer Scheibe (11 bis 14, 21, 35, 45, 53) besteht, die direkt zwischen zwei angrenzenden Wirbelkörpern zwischenlegbar ist und je nach Wirbellage parallele oder zueinander im Winkel stehende Auflageflächen hat.
2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Scheibe als Ringscheibe (35, 45, 53) mit regelmäßigem oder unregelmäßigem Umfang ausgebildet ist, und daß der Innenumfang der Scheibe einen vieleckigen oder unregelmäßigen Querschnitt hat.
3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Auflageflächen der Scheibe (14, 35, 53) Rauigkeiten, Porenwelligkeiten oder andere Unebenheiten aufweisen.
4. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Auflageflächen der Scheiben (14, 35, 53) herausragende Spitzen (20) aufweisen.
5. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (45) Kanäle (46) aufweist, in die Knochenzement oder Knochenmaterial einbringbar ist.

6. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (11 bis 14, 2135, 45, 53) aus faserverstärktem Kunststoff besteht und im Wickelverfahren oder ausaufgerollten Fasermatten hergestellt ist.
7. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (53) aus einem Strang (32, 33 bzw. 50) geschnitten ist.
8. Implantat nach Anspruch 7, dadurch gekennzeichnet, daß der Strang (32, 33 bzw. 50) aus unidirektionalen Fasern (32) und/oder Flechtlagen (33, 51) besteht.

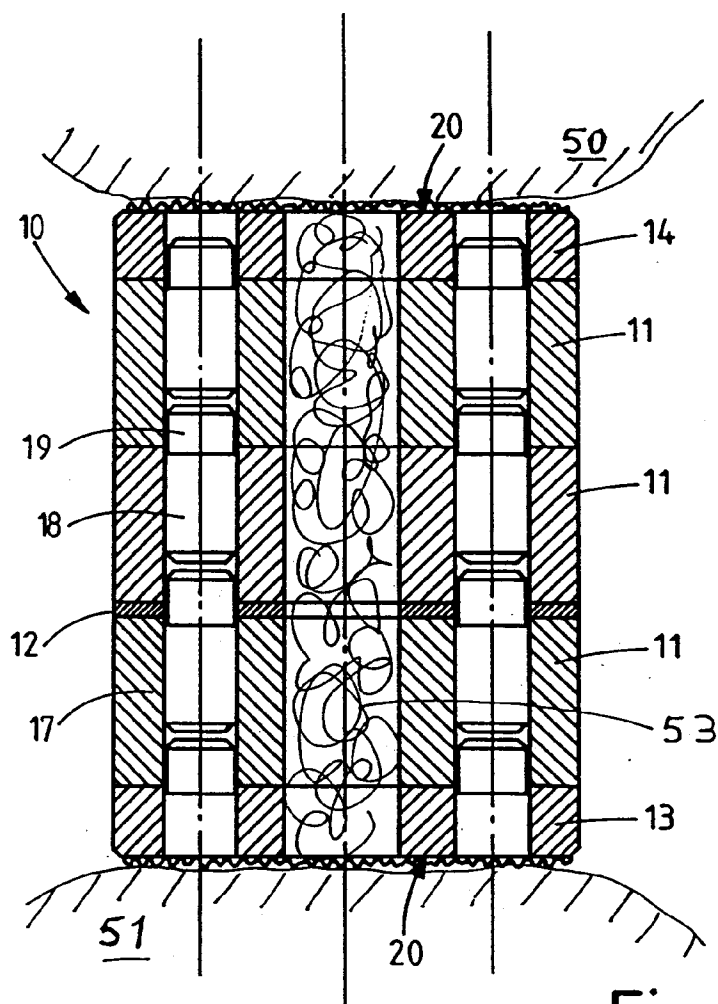


Fig. 1

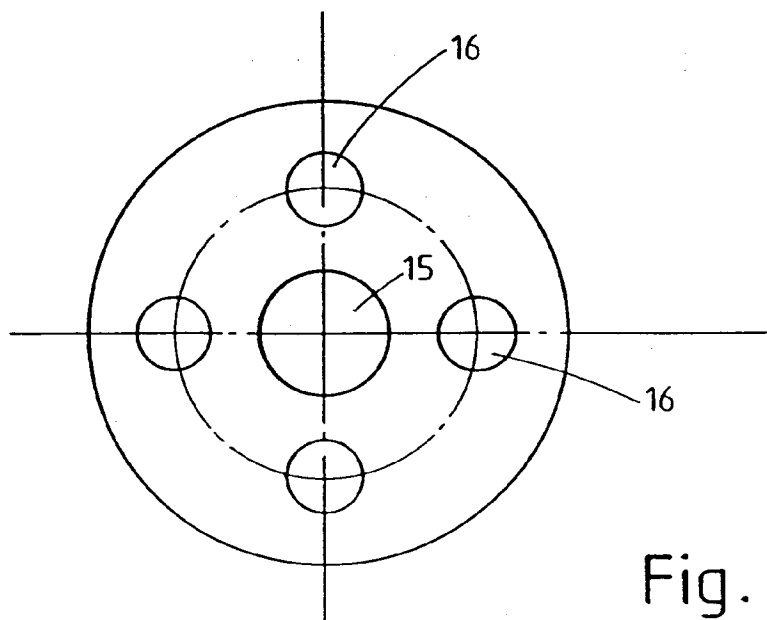


Fig. 2

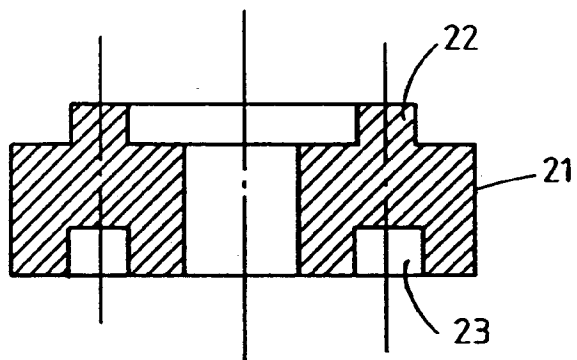


Fig. 3

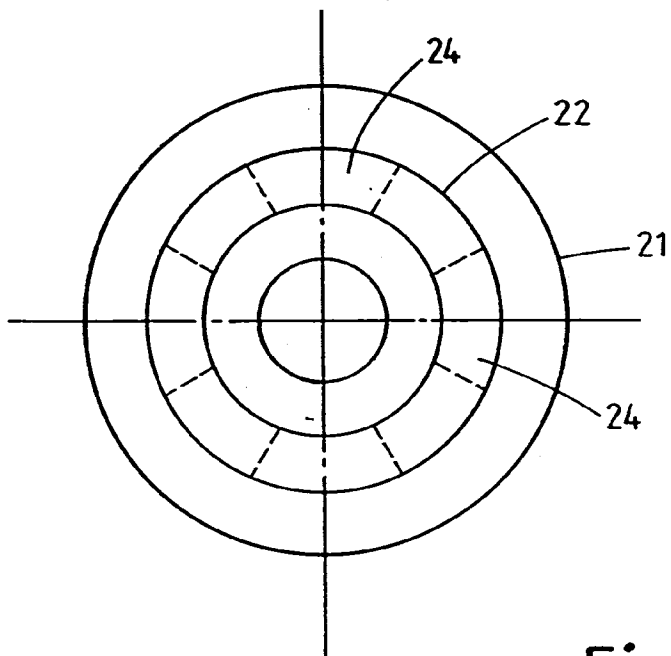


Fig. 4

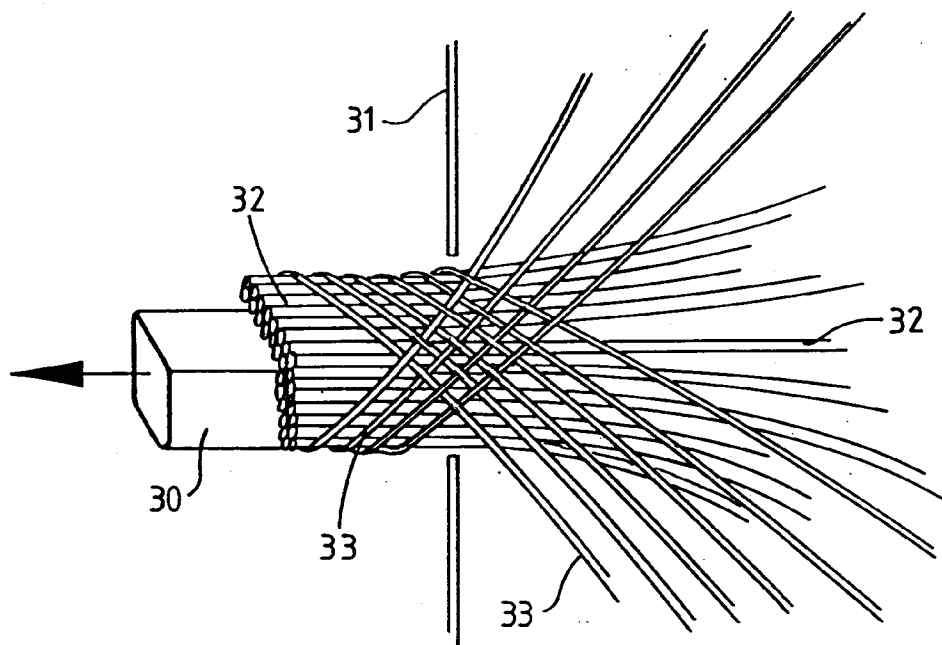


Fig. 5

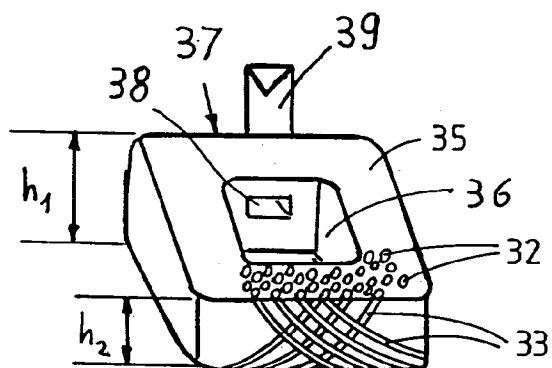


Fig. 6

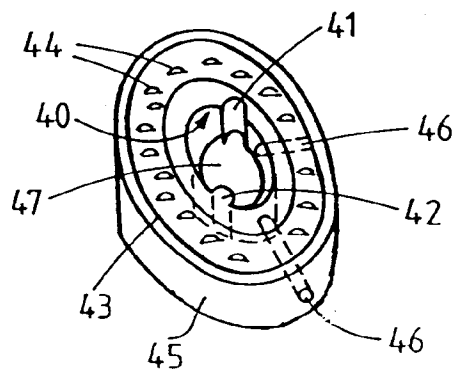


Fig. 7

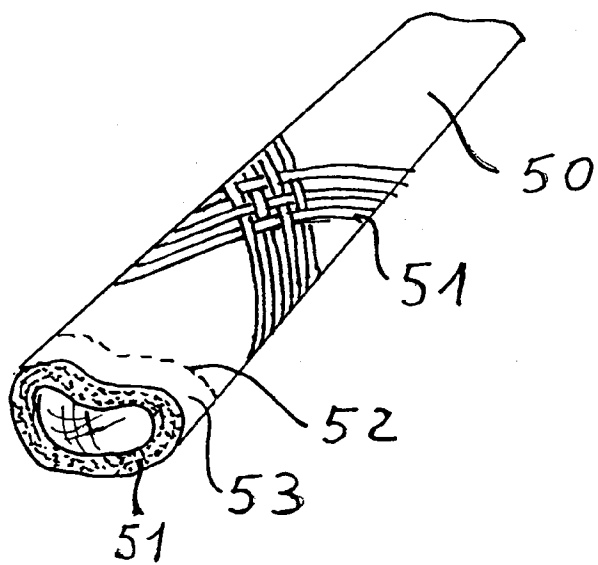


Fig.8

(19)



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(54) Composite structure and method of forming same

(57) A method of forming a composite structure (60) comprises the steps of forming a radially inner portion (64) of a preform with braided reinforcing fibers extending substantially transverse to an axis of the preform and forming a radially outer portion (68) of the preform circumscribing the inner portion with braided reinforcing fibers extending substantially parallel to the axis of the preform. The preform is heated and consolidated in a mold into the composite structure. The composite struc-

ture has braided reinforcing fibers extending throughout a radially inner portion (60) substantially transverse to an axis of the structure along which the structure is subject to splitting to resist splitting of the composite structure along the axis and braided reinforcing fibers extending throughout a radially outer portion (68) substantially parallel to the axis to resist bending of the composite structure. The composite structure is particularly suitable for manufacturing a bone plate.

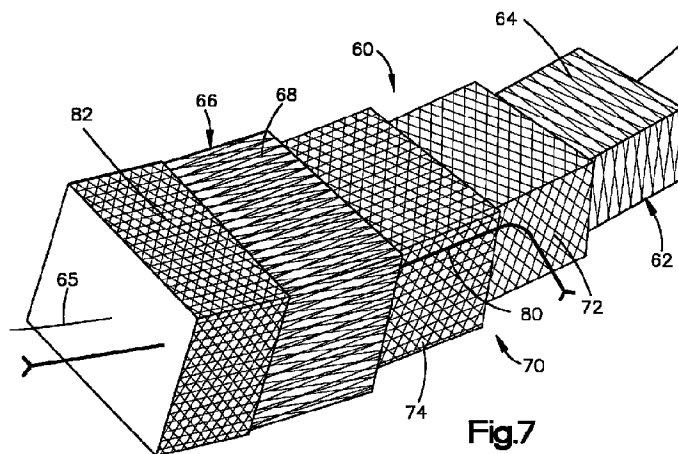


Fig.7

EP 0 706 876 A1

Description

Background of the Invention

5 The present invention relates to a composite structure, and in particular relates to a composite structure comprising matrix material with braided reinforcing fibers and a method of making the structure.

There are many known composite structures which comprise a fiber reinforced matrix material. A known composite structure comprises a laminated stack of layers of matrix material containing linearly oriented reinforcing fibers. The direction of orientation of the reinforcing fibers in one layer may be at a different angle relative to the direction of orientation of the reinforcing fibers in an adjacent layer. A disadvantage of a laminated stack of layers of a matrix material containing linearly oriented reinforcing fibers is that there is no fiber reinforcement in a direction perpendicular to the layers. A known way to strengthen the structure in the direction perpendicular to the layers is to stitch the layers together. A disadvantage in stitching the layers together is that the stitching process is labor and equipment intensive. Also, known fiber reinforced composite structures are made from knitted fibers and woven fibers which form a three-dimensional structure. However, the making of these composite structures is also labor and equipment intensive.

Summary of the Invention

10 In accordance with the present invention, a composite structure is made by a method which comprises the steps of braiding reinforcing fibers of a radially inner portion of a preform to extend substantially transverse to an axis of the preform along which the composite structure is subject to splitting. Reinforcing fibers of a radially outer portion circumscribing the radially inner portion are braided to extend substantially parallel to the axis of the preform. The preform is placed in a mold and heated to a temperature at which fibers which are to become the matrix material melt but the reinforcing fibers do not melt. The preform is consolidated in the mold. After heating and consolidating the preform, the composite structure is cooled so that a device such as a bone plate can be machined from the composite structure.

25 The composite structure comprises a radially inner portion of matrix material with braided reinforcing fibers extending throughout the inner portion substantially transverse to an axis of the composite structure along which the composite structure is subject to splitting to resist splitting of the composite structure. A radially outer portion of matrix material circumscribes the inner portion and has braided reinforcing fibers extending throughout the outer portion substantially parallel to the axis to resist bending of the composite structure.

30 The composite structure is similar to an I-beam in bending. The radially outer portions, like the outer webs of an I-beam, need the strength to resist bending of the composite structure because the stresses due to the bending are concentrated in the radially outer portions. The radially inner portion, like the connecting web of the I-beam, does not need to resist bending. The radially inner portion can be used to resist splitting of the composite structure.

35 The composite structure is machined into a bone plate for maintaining adjacent bone members, such as vertebrae or pieces of a broken bone, in a desired spatial relationship. When fasteners extend through openings in the bone plate to connect the bone plate to bone, the bone plate is subjected to clamping forces which could cause the bone plate to split along an axis. The braided reinforcing fibers in the radially inner portion of matrix material resist splitting of the bone plate due to the clamping forces applied to the bone plate by the fasteners. Furthermore, the braided reinforcing fibers extending through the radially outer portion resist bending of the bone plate and prevent movement between adjacent bone members which the bone plate is connected to.

40 A composite bone plate, as compared to a metal bone plate, is advantageous because it does not block the image of tissue on X-ray films and computerized tomography scans. A doctor can easily see if the pieces of a broken bone to which the composite bone plate is connected are healing properly or if adjacent vertebrae to which the composite bone plate is connected are fusing together properly. An X-ray marker, such as a titanium wire, may be braided into the composite bone plate so that a doctor may determine the position of the bone plate.

45 Another advantage of the composite bone plate is that the plate can be designed to prevent stress shielding. The stress-strain curve for bone has an initial region where some strain is achieved with very little stress. This initial region of the stress-strain curve is often called the "toe" of the stress-strain curve. At higher stresses, the curve becomes linear or proportional. The "toe" region allows for some deformation of the bone at low stress levels, while becoming more rigid at higher stresses, protecting against higher loads. The low stress deformation of bone is important in bone remodeling since the bone remodels to support applied loads.

50 When stiff metallic implants are connected to bone, the surrounding bone is shielded from applied stresses and the bone resorbs. If flexible implants are used, at high loads, the bone is deformed too much and damaged. The composite structure of the present invention is well suited for use as a bone plate since it can be made to have a stress-strain curve similar to that of bone, that is, with a low-stress "toe" region.

55 Contorted reinforcing fibers may be used in the composite structure to increase the size of the "toe" region. Twisted commingled yarn may be used in braiding the preform or the reinforcing fibers may be coiled, wavy, or kinked. With these

structures, the matrix material of the bone plate deforms at low stress levels while the reinforcing fibers begin to straighten out. At higher stress levels, the reinforcing fibers straighten out to pick up the load and the composite plate becomes stiffer.

Brief Description of the Drawings

The foregoing and other features of the present invention will become apparent to one skilled in the art upon consideration of the following description of the preferred embodiments of the invention with reference to the accompanying drawings, wherein:

Fig. 1 is a fragmentary view of a portion of a spinal column on which a composite bone plate constructed in accordance with the present invention has been installed to maintain vertebrae in a desired spatial relationship; Fig. 2 is a sectional view, taken generally along the line 2-2 of Fig. 1, illustrating the manner in which fasteners are used to connect the composite bone plate with the vertebrae; Fig. 3 is a plan view of the composite bone plate of Fig. 1; Fig. 4 is a sectional view of the composite bone plate of Fig. 3 taken along the line 4-4 of Fig. 3; Fig. 5 is a schematic view of a preform, partially cut away to show various layers of the preform, used in forming the composite bone plate of Fig. 1; Fig. 6 is an enlarged plan view of a portion of a layer of the preform of Fig. 5; Fig. 7 is a schematic perspective view of a composite structure, partially cut away to show various portions of the structure, from which the bone plate of Fig. 1 is machined; and Fig. 8 is a graph showing the relationship between stress and strain for the composite structure of Fig. 7.

Description of the Preferred Embodiments of the Invention

A pair of surgically implantable composite bone plates 10 (Fig. 1) for correcting deformation and/or degeneration of a spinal column C are connected with several vertebrae V of the spinal column by fasteners 20. Each composite bone plate 10 is elongate and has a rectangular cross-section taken in a plane extending perpendicular to a longitudinal central axis 12 of the plate (Fig. 2). Each composite plate 10 is preferably curved to conform to a desired curvature of the spinal column C, as illustrated in Fig. 4. The composite bone plates 10 have sufficient strength and rigidity to maintain the vertebrae V in the desired relationship. Although the composite bone plates are shown maintaining vertebrae in a desired spatial relationship, they may be used for maintaining pieces of a broken bone in a desired relationship.

The composite bone plates 10 are connected to respective vertebrae V by fasteners 20 (Fig. 2) made of a suitable biocompatible material, such as titanium or stainless steel. Each of the fasteners 20 has a threaded inner end portion 22 having a coarse helical thread convolution 24 which engages the vertebra V. An outer end portion 26 of the fastener 20 is provided with a relatively fine thread which engages an internal thread convolution on a clamp nut 28 preferably made of a suitable biocompatible material, such as titanium coated with titanium nitride. Wrenching flats (not shown) are provided on the outermost end of the outer end portion 26 of the fastener 20. Torque is applied to these wrenching flats to turn the relatively coarse helical thread convolution 24 into the vertebra V. Once the fastener 20 has been connected to the vertebra and the composite bone plate 10, the outer end portion of the fastener may be cut away to minimize the overall length of the fastener.

An intermediate portion 32 is provided with wrenching flats which can be engaged to hold the fastener 20 against rotation when the clamp nut 28 is tightened. In addition, the intermediate portion 32 of the fastener has a flat outer side surface which abuttingly engages the composite bone plate 10. When the clamp nut 28 is tightened, the composite bone plate 10 is securely gripped between the clamp nut 28 and the intermediate portion 32 of the fastener 20.

Although it is contemplated that the fastener 20 could have many different constructions, it is preferred to construct the fastener 20 in accordance with U.S. Patent No. 4,854,311 which is assigned to the assignee of the present invention. Another possible fastener would include a piece with a plurality of ridges that mates with a plurality of ridges on the plate to prevent movement of the plate relative to the fastener.

Each of the composite bone plates 10 has a length which is at least sufficient to enable the bone plate to span at least two of the vertebrae V. In the embodiment of the invention illustrated in Fig. 1, the bone plates 10 span two vertebrae V. Of course, the length of the composite bone plates in any particular installation will depend upon the condition to be corrected and the number of vertebrae V to be held in a desired spatial relationship relative to each other by the composite bone plates. Preferably, each of the composite bone plates includes a titanium wire 80 (Fig. 2) extending along the longitudinal extent of the bone plate as an X-ray marker.

Each of the composite bone plates 10 is identical and includes at least one slot 40 (Figs. 3 and 4) and may include a circular opening 42 located adjacent an end portion of the bone plate. The bone plate 10 may have any number of slots for receiving fasteners depending on the length of the bone plate. The bone plate 10 has an upper surface 44 provided with spherical recesses 46 along the slot 40 defining a plurality of locations for receiving the fastener 20. If the bone plate 10 includes a circular opening 42, then upper surface 44 also includes a spherical recess 48 surrounding

the opening 42 for receiving a fastener 20. The spherical recesses 46 and 48 have a radius that is the same as a radius of a spherical surface of the clamp nut 28 and is approximately 16mm. The spherical recesses extend approximately 145° to help prevent splitting of the plate along the longitudinal axis 12 by directing most of the clamping forces applied to the plate in a direction normal to the surface 44 instead of transverse to the axis 12.

5 Preferably, a composite structure 60 from which the bone plate 10 is machined is formed by heating and consolidating a cylindrical braided preform 100 (Fig. 5) having a longitudinal axis 101. The preform 100 has a cross-section that forms a cross-section of a single composite structure 60 upon heating and consolidating the preform. The preform 100 may have any desired length to form one or a plurality of composite structures 60.

10 The preform 100 comprises a plurality of concentric layers of braided commingled yarn. The layers have varying braid angles with the inner layers having a large braid angle and the outer layers having a relatively small braid angle. The braid angle X is defined as half of the interlacing angle between yarns such as A and B, as shown in Fig. 6.

15 Preferably, the yarn is a commingled yarn known as Ultrapek/AS-4 Commingled Yarn manufactured by Cytac Inc., Anaheim, CA. Ultrapek/AS-4 Commingled Yarn comprises Ultrapek polymer fibers made from poly(ether ketone ether ketone) by BASF Inc., Charlotte, NC commingled with AS-4 carbon fibers made from a polyacrylonitrile precursor by Hercules Advanced Materials and Systems Company, Magna, UT. The carbon fibers are the reinforcing fibers and the polymer fibers become matrix material when melted. Preferably, the reinforcing fibers are between 55% and 75% of the weight of the preform 100.

20 Alternatively, the material of which the yarn is made may be carbon fibers that have firmly adhering polymer powder bonded to the carbon fibers. Also, the material of which the yarn is made may be carbon fibers having a thin coating of polymer material. Also, the carbon fibers may be replaced with other carbon or graphite fibers or with glass fibers, silicon carbide fibers, or any other structural fibers. Also, the Ultrapek polymer may be replaced with other high performance and biocompatible polymers. These include, but are not limited to, other poly (aryl ether ketone)s such as PEEK, PEKK, and PEK, as well as poly (amide imide)s, poly (aryl sulfone)s, nylon, poly (butylene phthalate), poly (ethylene phthalate) and liquid crystal polymers or other similar polymers.

25 The preform 100 includes a radially inner plurality of concentric layers 102, one of which is shown in Figs. 5 and 6, of biaxially braided commingled yarn. The braid angle X of each of the layers 102 is between approximately 60° and 90°. It is desirable to have the braid angle as close to 90° as possible. Preferably, the inner plurality of concentric layers 102 comprises approximately one third of the thickness of the preform 100. The number of layers and the actual braid angle may vary depending on the braiding process.

30 An intermediate plurality of concentric layers 104 and 106 of braided yarn circumscribes the radially inner plurality of concentric layers 102. The braid angle of each of the layers of the intermediate plurality of concentric layers 104 and 106 is between approximately 40° and approximately 55°. The intermediate plurality of layers includes a first plurality of concentric layers 104, one of which is shown in Fig. 5, of biaxially braided yarn and a second plurality of concentric layers 106, one of which is shown in Fig. 5, of triaxially braided yarn circumscribing the first plurality of layers. Triaxially braided yarn has a pattern similar to the pattern of biaxially braided yarn shown in Fig. 6 with another system of yarn extending parallel to the longitudinal axis 101 of the preform 100 braided between the yarn extending transverse to the longitudinal axis.

35 The titanium wire 80 is braided into one of the second plurality of layers 106. Preferably, the intermediate plurality of layers 104 and 106 comprises approximately one third of the thickness of the preform 100. The actual number of intermediate layers 104 and 106 and the braid angle of the intermediate layers 104 and 106 may vary depending on the braiding process.

40 A radially outer plurality of concentric layers 110, one of which is shown in Fig. 5, of triaxially braided yarn circumscribes the intermediate plurality of layers 104 and 106. The braid angle of each of the layers of the outer plurality of concentric layers 110 is between approximately 0° and approximately 45°. It is desirable to have the braid angle as close to 0° as possible. Preferably, the outer plurality of concentric layers 110 comprises approximately one third of the thickness of the preform 100. The number of outer layers 110 and the actual braid angle of outer layers 110 may vary depending on the braiding process.

45 A radially outermost concentric layer 112 of triaxially braided yarn circumscribes the radially outer plurality of concentric layers 110. The outermost layer 112 has a braid angle of between approximately 40° and approximately 65°. The outermost layer 112 is tightly braided together so it does not come apart easily to provide for easy handling of the preform 100. Preferably, approximately half of the bias ends of the outermost layer 112 comprises a polymer yarn, the other half of the bias ends comprises Ultrapek/AS-4 commingled yarn and the axial ends comprise Ultrapek/AS-4 commingled yarn to provide a polymer rich surface of the composite structure 60.

50 Preferably, at least some of the reinforcing fibers are contorted prior to braiding the preform. The commingled yarn may be twisted, or coils, waves, or kinks may be formed in the reinforcing fibers. Therefore, the stress-strain curve (Fig. 7) of the composite structure has a "toe" region 200 and a linear region 202. At low stress levels the stress-strain curve is non-linear and at higher stress levels the stress and strain are approximately proportional. At low stresses the matrix material of the composite structure 60 deforms while the reinforcing fibers straighten out and at higher stresses the reinforcing fibers straighten and pick up the load.

EXAMPLES

Two examples of braided preforms from which composite bone plates have been formed are set forth below in Tables 1 and 2. The tables set out each concentric layer of the preform numbered from the radially innermost layer to the radially outermost layer. The braid angle and the picks per inch (ppi) for each layer are given in the tables. The picks per inch is defined as the distance between interlacing points and is labeled Y in Fig. 6.

TABLE 1

Layer	Braid Angle (deg.)	ppi
1	14	14
2	47	13
3	54	12
4	64	14
5	60	9
6	62	9
7	65	9
8	65	8
9	66	8
10	70	9
11	71	9
12	70	8
13	71	8
14	72	8
15	73	8
16	65	5
17	66	5
18	47	10
19	45	8
20	48	8.5
21	43	7
22	45	7
23	45	6.25
24	46	6.25
25	45	5.75
26	45	5.25
27	45	5
28	60	5

Layers 1-17 are biaxially braided with 4 bias ends. Layers 18-21 are biaxially braided with 16 bias ends. Layers 22 and 23 are triaxially braided with 16 bias ends and 16 axial ends. Layer 22 includes a bias end of titanium wire. Layers

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24-27 are triaxially braided with 16 bias ends and 32 axial ends. Layer 28 is triaxially braided with 8 bias ends of commingled yarn, 24 bias ends of polymer yarn, and 48 axial ends of commingled yarn.

TABLE 2

Layer	Braid Angle (deg.)	ppi
1	33.4	14
2	50.8	13
3	65.5	14
4	71.4	14
5	72.2	12
6	74	12
7	75.8	12
8	77.8	12
9	59.1	4
10	60.1	4
11	54.7	4
12	44.1	2
13	44.8	2
14	45.1	8
15	26.6	3.5
16	25	3
17	26.6	3
18	30.1	3
19	22.2	2
20	28.8	2.5
21	30.2	2.5
22	64.2	7

Layers 1-13 are biaxially braided with 4 bias ends. Layers 14 and 15 are triaxially braided with 16 bias ends and 16 axial ends. Layer 14 includes an axial end of titanium wire. Layers 16-21 are triaxially braided with 16 bias ends and 32 axial ends. Layer 22 is triaxially braided with 8 bias ends of commingled yarn, 8 bias ends of polymer yarn, and 48 axial ends of commingled yarn.

In both examples the first few radially innermost layers have braid angles from 14° to 54°. These braid angles are a result of the braiding process and machinery. It is preferred that these innermost layers have a braid angle as close to 90° as possible.

After the preform 100 is formed, it is heated and consolidated into an elongate composite structure 60 from which the bone plate 10 is machined. The preform 100 may be cut into a plurality of lengths to form a plurality of composite structures 60. The preform 100 is placed into a mold and the mold is placed into a high temperature consolidation press with vacuum capability. The vacuum chamber of the press is evacuated, the temperature is set to 800°F, and the pressure is set to 500 lbs. closing force. It requires approximately one hour for the press to reach 800°F. As the press displacement decreases, showing consolidation of the preform, the pressure is increased to 7,000 lbs. The temperature and pressure are maintained for 45 minutes and then the heat is turned off and the press cooling is turned on. After the mold has reached ambient temperature, the press is opened, the mold is removed, and the consolidated composite structure 60

is removed from the mold. The composite structure 60 is then machined to form a desired bone plate 10. After the bone plate 10 is machined it is placed in an ultrasonic bath with acetone to remove any residual particulate debris.

The composite bone plate 10 is machined from the composite structure 60 (Fig. 7) comprising matrix material and reinforcing fibers. Preferably, the composite structure 60 is curved if the bone plate 10 is to be curved. The matrix material is the polymeric material, Ultrapek, and the reinforcing fibers are the AS-4 carbon fibers. Preferably, the reinforcing fibers make up between 55% and 75% of the weight of the composite structure 60.

The composite structure 60 includes a radially inner portion of matrix material 62 with a plurality of concentric layers 64, one of which is shown in Fig. 7, of biaxially braided reinforcing fibers extending throughout the inner portion. The reinforcing fibers in the radially inner portion of matrix material 62 extend substantially transverse to a longitudinal axis 65 of the composite structure 60 to resist splitting of the structure along the longitudinal axis 65 when connected to bone as a bone plate. The axis 65 of the composite structure 60 becomes the axis 12 of the bone plate 10. The reinforcing fibers in the radially inner portion 62 have a braid angle between approximately 60° and 90°. It is desirable to have the braid angle as close to 90° as possible.

The composite structure 60 has a radially outer portion of matrix material 66 which circumscribes the radially inner portion of matrix material 62. A plurality of concentric layers 68, one of which is shown in Fig. 7, of triaxially braided reinforcing fibers extend throughout the radially outer portion of matrix material 66 substantially parallel to the longitudinal axis 65 to resist bending of the composite structure. The reinforcing fibers in the outer portion 66 have a braid angle between 0° and approximately 45°. It is desirable to have the braid angle as close to 0° as possible.

The composite structure 60 also includes an intermediate portion of matrix material 70 circumscribing the inner portion of matrix material 62 and circumscribed by the outer portion of matrix material 66. A plurality of concentric layers 72 and 74 of braided reinforcing fibers extend throughout the intermediate portion 70 and have a braid angle between approximately 40° and approximately 55°. A first plurality of concentric layers 72, one of which is shown in Fig. 7, of braided reinforcing fibers of the intermediate portion 70 are biaxially braided. A second plurality of concentric layers 74, one of which is shown in Fig. 7, of braided reinforcing fibers of the intermediate portion 70 circumscribes the first plurality of concentric layers 72 of the intermediate portion and are triaxially braided. The titanium wire 80 extends through the intermediate portion 70 and substantially parallel to the longitudinal axis 65 of the composite structure 60 to act as an X-ray marker.

The composite structure 60 has a radially outermost layer 82 of braided reinforcing fibers. The radially outermost layer 82 circumscribes the radially outer portion of matrix material 66. The radially outermost layer 82 is triaxially braided and has a braid angle between approximately 40° and approximately 60°.

From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications. Such improvements, changes and modifications within the skill of the art are intended to be covered by the appended claims.

Claims

1. A composite structure comprising:
 - a radially inner portion of matrix material;
 - a radially outer portion of matrix material circumscribing said inner portion;
 - braided reinforcing fibers extending throughout said inner portion substantially transverse to an axis along which said composite structure is subject to splitting to resist splitting of said composite structure along said axis; and
 - braided reinforcing fibers extending throughout said outer portion substantially parallel to said axis to resist bending of said composite structure;
 - said directions of said reinforcing fibers resulting from heating and consolidating a preform made of matrix material and braided reinforcing fibers.
2. A composite structure as set forth in claim 1 wherein said reinforcing fibers in said inner portion have a braid angle between approximately 60° and 90° and said reinforcing fibers in said outer portion have a braid angle between 0° and approximately 45°.
3. A composite structure as set forth in claim 2 further including an intermediate portion of matrix material circumscribed by said outer portion of matrix material and circumscribing said inner portion of matrix material and braided reinforcing fibers extending throughout said intermediate portion, said reinforcing fibers in said intermediate portion having a braid angle between approximately 40° and approximately 55°.
4. A composite structure as set forth in claim 3 wherein each of said inner, intermediate, and outer portions includes a plurality of concentric layers of braided reinforcing fibers.

5. A composite structure as set forth in claim 4 wherein said plurality of concentric layers of reinforcing fibers in said inner portion are biaxially braided.
6. A composite structure as set forth in claim 5 wherein said intermediate portion includes a first plurality of concentric layers of biaxially braided reinforcing fibers and a second plurality of concentric layers of triaxially braided reinforcing fibers, said second plurality of concentric layers of reinforcing fibers circumscribing said first plurality of concentric layers of reinforcing fibers in said intermediate portion.
7. A composite structure as set forth in claim 6 wherein said plurality of concentric layers of reinforcing fibers in said outer portion are triaxially braided.
8. A composite structure as set forth in claim 3 further including a titanium wire extending through said intermediate portion.
9. A composite structure as set forth in claim 2 further including a radially outermost portion circumscribing said outer portion, said outermost portion including braided reinforcing fibers with a braid angle between approximately 40° and approximately 65°.
10. A composite structure as set forth in claim 1 including a plurality of openings for receiving fasteners.
11. A composite structure as set forth in claim 10 wherein said openings are defined by spherical recesses in a side surface of said composite structure which define a plurality of locations for receiving fasteners, each of said recesses defining a spherical arc extending approximately 145°.
12. A composite structure as set forth in claim 11 wherein at least one of said openings is a slot, said recesses defining a plurality of locations along said slot for receiving fasteners.
13. A composite structure as set forth in claim 12 further including a round opening located at an axial end portion of said structure.
14. A composite structure as set forth in claim 1 wherein said reinforcing fibers are between 55% and 75% of the weight of said composite structure.
15. A composite structure as set forth in claim 1 wherein at least some of said reinforcing fibers are contorted.
16. A composite structure as set forth in claim 15 wherein said at least some of said reinforcing fibers are coiled.
17. A composite structure as set forth in claim 15 wherein said at least some of said reinforcing fibers are twisted.
18. A method of forming a composite structure which in use is subject to splitting along an axis and bending, said method comprising the steps of:
 - providing a radially inner portion of a preform with a first plurality of braided reinforcing fibers extending substantially transverse to the axis;
 - providing a radially outer portion of the preform circumscribing the inner portion with a second plurality of braided reinforcing fibers extending substantially parallel to the axis; and
 - heating and consolidating the preform to form a matrix with the first and second plurality of braided reinforcing fibers extending through inner and outer portions of the matrix material, respectively.
19. A method as set forth in claim 18 including braiding the first plurality of reinforcing fibers of the inner portion of the preform with a braid angle between approximately 60° and 90° and braiding the second plurality of reinforcing fibers of the outer portion with a braid angle between 0° and approximately 45°.
20. A method as set forth in claim 19 including providing an intermediate portion of the preform circumscribed by the outer portion and circumscribing the inner portion with a third plurality of braided reinforcing fibers having a braid angle between approximately 40° and approximately 55°.
21. A method as set forth in claim 20 including providing a radially outermost portion of the preform circumscribing the outer portion with braided reinforcing fibers having a braid angle between approximately 40° and approximately 65°.

22. A method as set forth in claim 21 including braiding approximately 50% of bias ends of the radially outermost portion with matrix yarn, approximately 50% of the bias ends of the radially outermost portion with commingled matrix and reinforcing fiber yarn, and axial ends of the radially outermost portion with commingled matrix and reinforcing fiber yarn.

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23. A method as set forth in claim 20 including forming each of the inner, intermediate, and outer portions to be approximately one third the thickness of the preform.

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24. A method as set forth in claim 20 including forming each of the inner, intermediate, and outer portions out of a plurality of concentric layers of braided fibers.

25. A method as set forth in claim 24 including biaxially braiding the plurality of concentric layers of the inner portion.

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26. A method as set forth in claim 24 including biaxially braiding a first plurality of concentric layers of the intermediate portion and triaxially braiding a second plurality of concentric layers of the intermediate portion circumscribing the first plurality of concentric layers of the intermediate portion.

27. A method as set forth in claim 24 including triaxially braiding the plurality of concentric layers of the outer portion.

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28. A method as set forth in claim 24 including braiding a titanium wire into the intermediate portion.

29. A method as set forth in claim 18 including contorting at least some of the reinforcing fibers prior to braiding.

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30. A method as set forth in claim 29 wherein said step of contorting the reinforcing fibers includes forming coils in the reinforcing fibers.

31. A method as set forth in claim 29 including forming the preform with commingled yarn.

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32. A method as set forth in claim 31 wherein the step of contorting the reinforcing fibers includes twisting the commingled yarn.

33. A method as set forth in claim 18 including forming a plurality of openings in the composite structure for receiving fasteners.

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34. A method as set forth in claim 33 including forming spherical recesses extending approximately 145° in a side surface of the composite structure to define a plurality of locations for receiving fasteners.

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35. A method as set forth in claim 34 including forming a slot with at least two recesses defining locations for receiving fasteners.

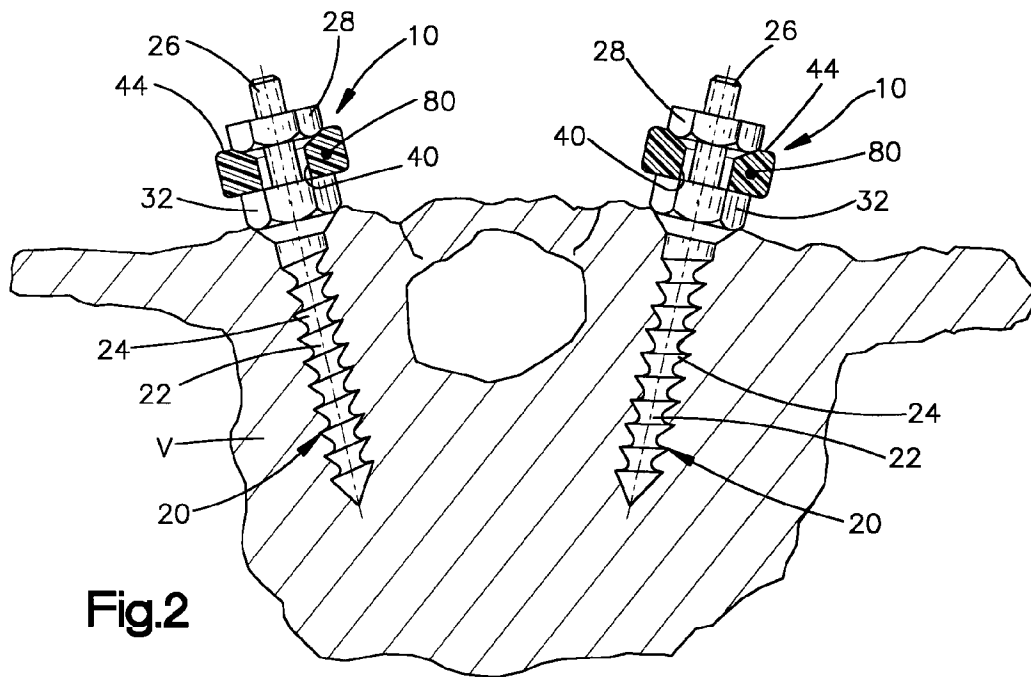
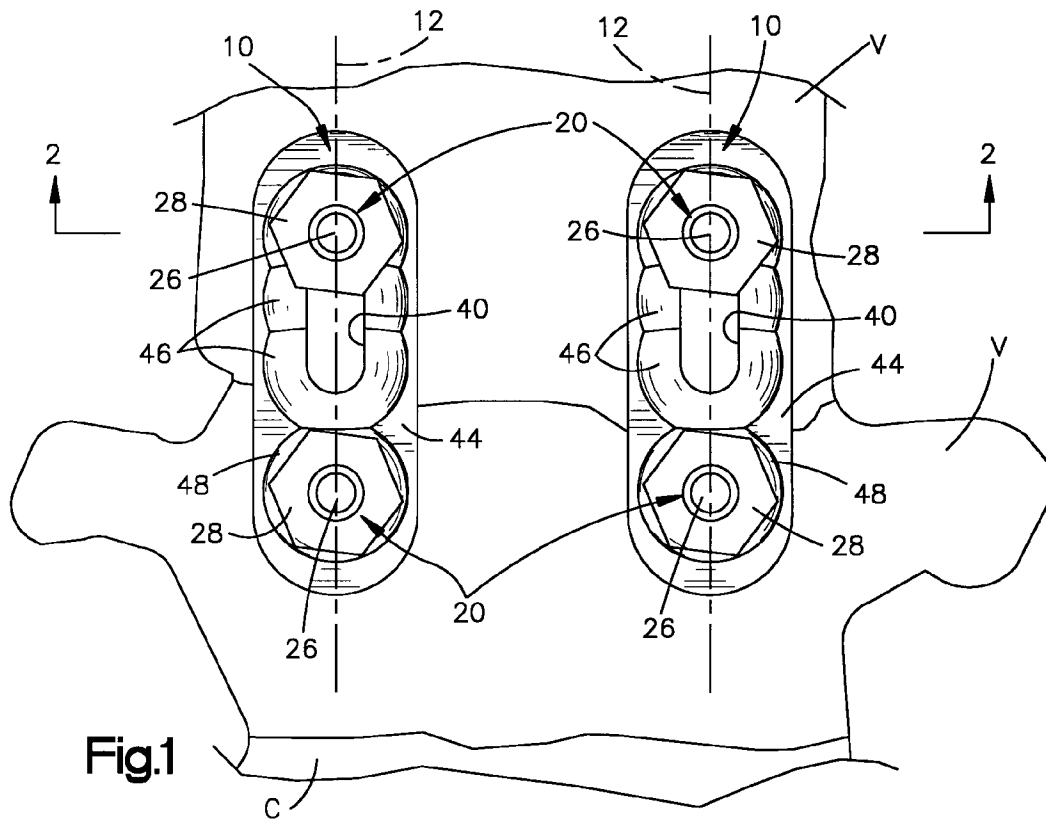
36. A method as set forth in claim 35 including forming a round opening at an axial end portion of the composite structure for receiving one fastener.

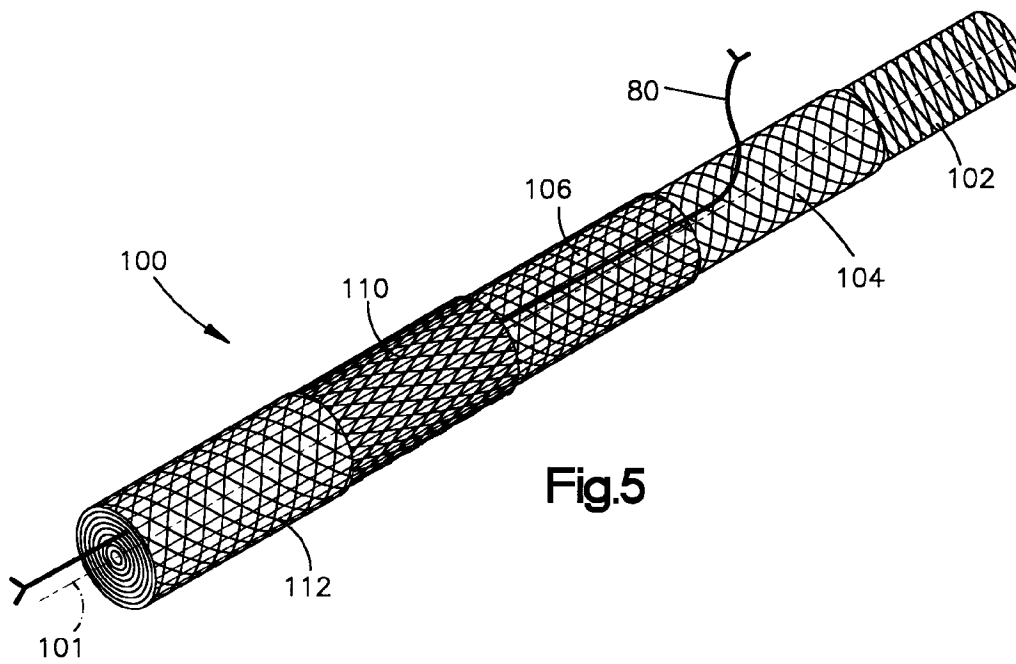
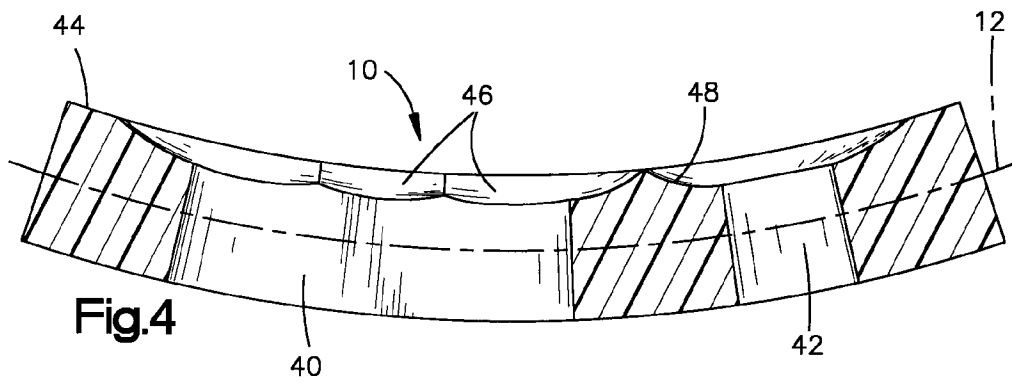
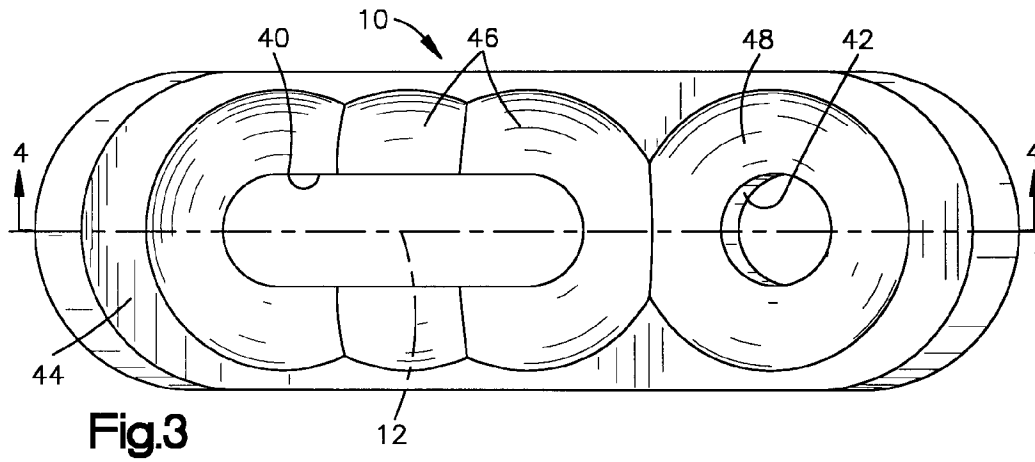
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37. A method as set forth in claim 18 further including forming the composite structure with the reinforcing fibers making up between 55% and 75% of the weight of the composite structure.

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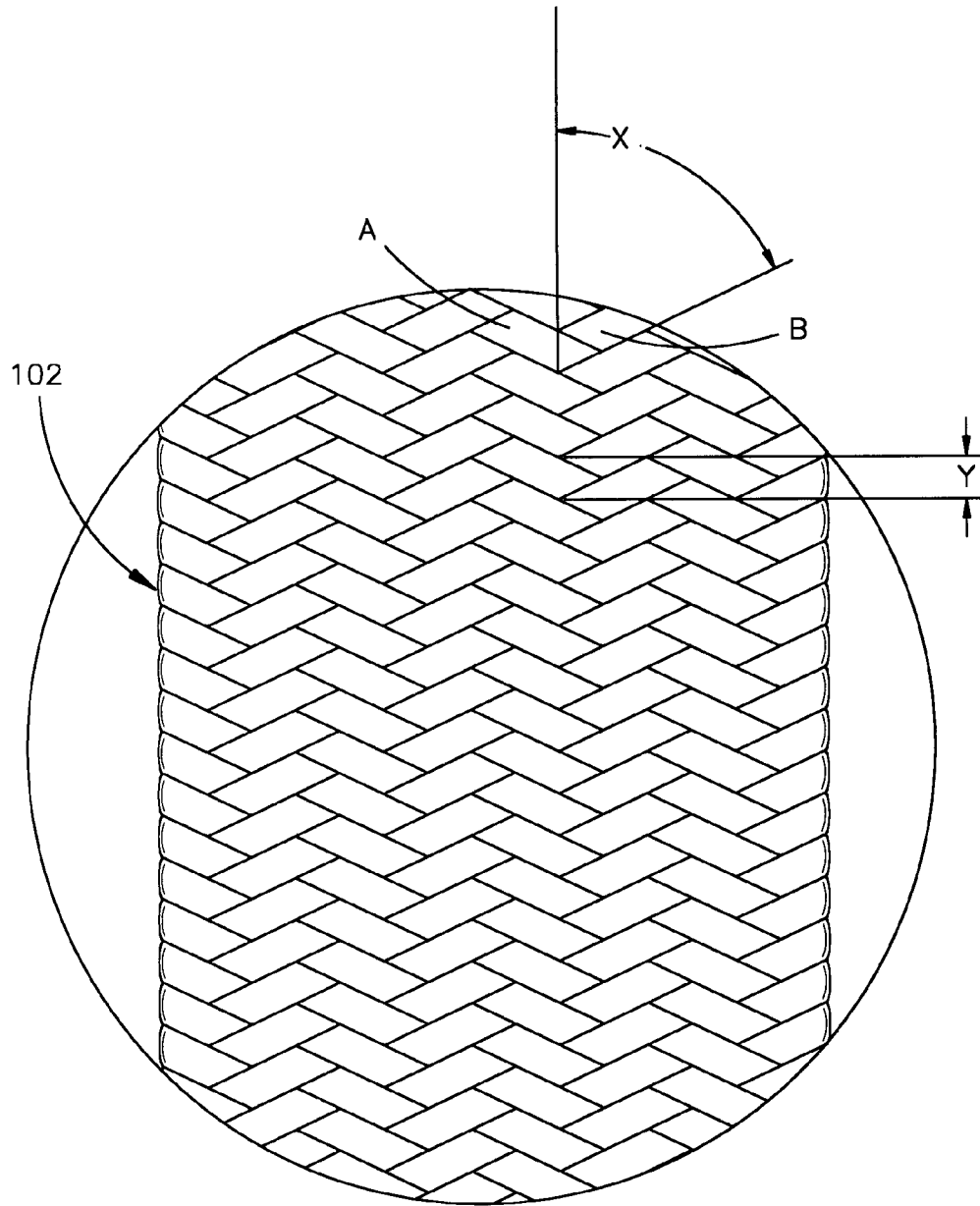
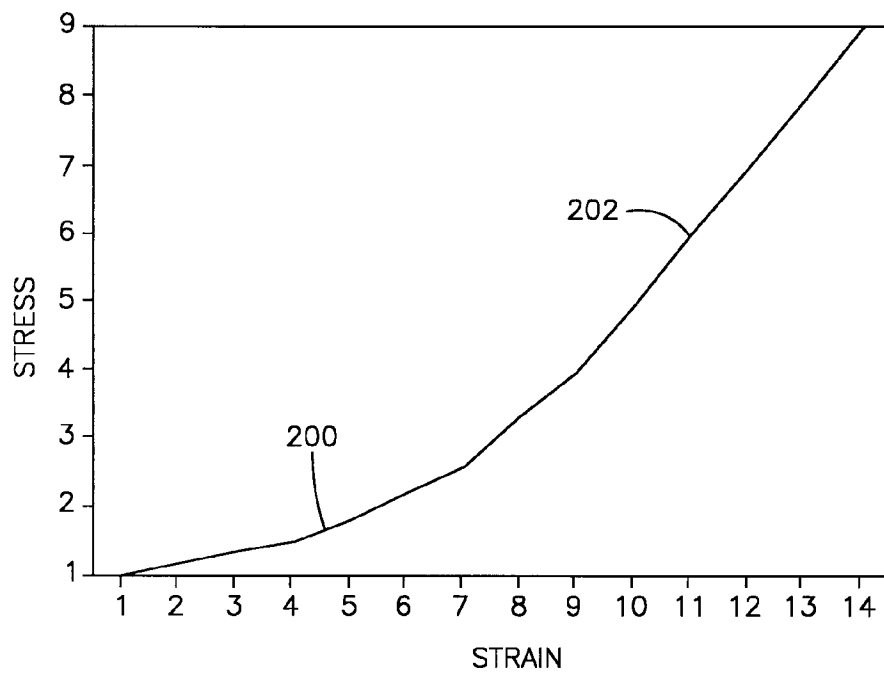
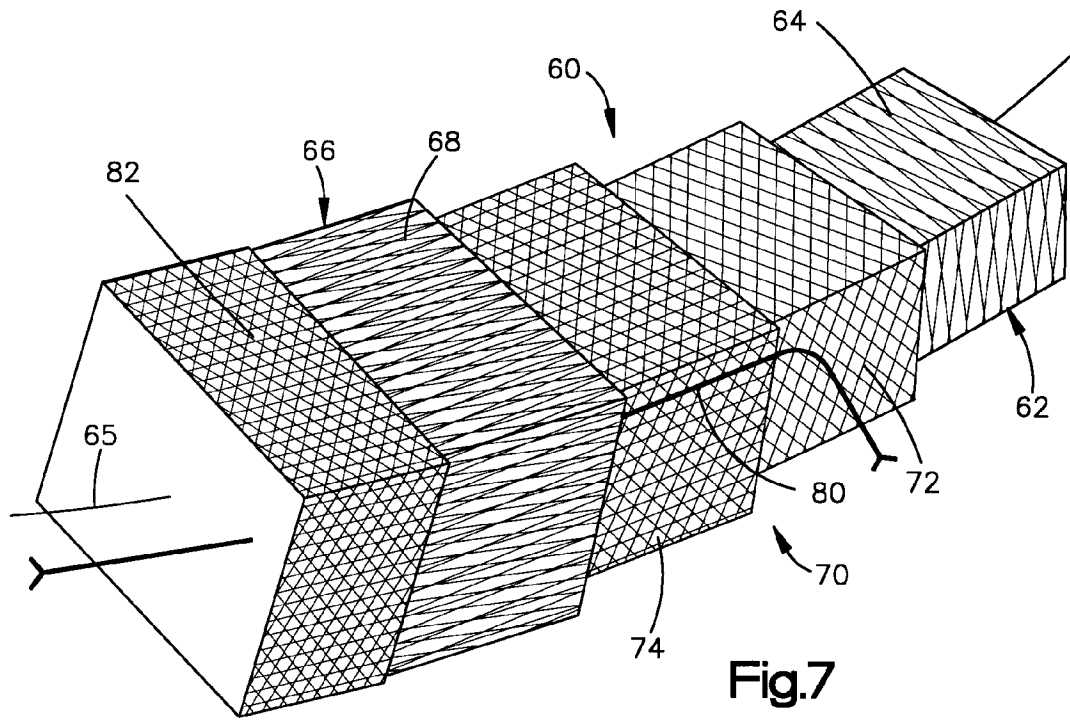


Fig.6





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 95 11 4530

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	EP-A-0 285 156 (DU PONT) 5 October 1988 * example 1 * ---	18-21, 23-27, 37	B29C70/34 B29C70/22 B29B11/16
X	WO-A-93 13733 (DU PONT) 22 July 1993	1-5, 9, 14	
Y	* page 19, line 29 - page 21, line 5; claims 20, 21 * ---	18-21, 23-27, 37	
X	WO-A-93 19699 (HOWMEDICA) 14 October 1993	1-5, 9, 14	
Y	* page 9, line 17 - line 34 * * page 3, line 29 - line 31 * ---	18-21, 23-27, 37	
X	EP-A-0 127 553 (VERRE TISSE SA) 5 December 1984 * the whole document * ---	1-5, 9, 14	
A	WO-A-92 11128 (ALLIED SIGNAL INC) 9 July 1992 * the whole document * -----	6, 7, 26, 27	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			B29C B29B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 30 January 1996	Examiner Van Wallene, A
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application I : document cited for other reasons & : member of the same patent family, corresponding document			

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(54) Conically-shaped fusion cage and method of implantation

(57) A fusion cage 20 for vertebral body fusion is conically-shaped. A thread 40 is formed as part of the external conical surface of the fusion cage. Apertures 54 are defined through the fusion cage in order to provide for contact between the engaged vertebral bone struc-

tures and bone growth inducing substances packed within the fusion cage. The fusion cage is introduced and maintains or increases the lordosis between adjacent vertebral bone structures.

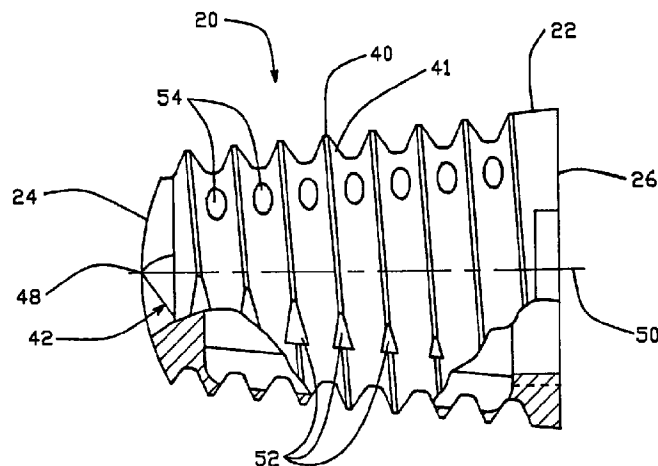


FIG. - 1

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Description

BACKGROUND

Field of the Invention

The present invention is directed to devices and methods for facilitating the fusing of bone structures and more particularly the fusing together of adjacent vertebral bodies or bone structures.

Background of the Invention

Technical literature and patent documents disclose a number of devices and methods for fusing bones together. One such device which has proven to be successful is disclosed in U.S. Patent 4,961,740, entitled "V-THREAD FUSION CAGE AND METHOD OF FUSING A BONE JOINT," which patent has been assigned the present assignee and which patent is incorporated herein by reference. The referenced patent discloses a fusion cage which is preferably cylindrical and has a thread formed as part of the external cylindrical surface. The fusion cage defines an internal cavity and apertures through the wall of the cage which communicate the external cylindrical surface with the internal cavity. The apertures are formed in the valleys of the thread. Normally two such cages are used to stabilize and fuse together adjacent vertebral bodies or bone structures.

In practice, using a posterior approach, a patient's vertebral bone structures are exposed and degenerate disk material located between the vertebral bone structures is removed. A threaded tap is used to tap a complementary thread in the upper and lower vertebral bone structures preparatory to the insertion of the above fusion cage. Once such tapping has been accomplished, using an introduction tool, the fusion cage is screwed into the space between the adjacent vertebral bone structures. The thread bites into the bone of the upper and lower vertebral bone structures, stabilizing the bone structures, and preventing the fusion cage from working out of this position due to patient movement. Generally two such fusion cages are applied using this technique. Once the two implants have been positioned, then bone growth inducing substances, such as bone chips, are packed into the internal cavity of the fusion cages. These bone growth inducing substances come into immediate contact with the bone from the vertebral bone structures which project into the internal cavity through the apertures. Such projection of bone is due to the fact that the apertures are formed in the valleys of the external thread of the fusion cage. Such immediate bone to bone contact between the vertebral bone structures and the bone pack within the fusion cages results in more rapid propagation of bone cells between the adjacent vertebral bone structures and thus a more rapid fusion of the adjacent vertebral bone structures.

It is to be understood that in the above method, bone growth inducing substances can be prepacked into the

cages before the cages are implanted between the vertebral body structures.

Summary of the Invention

The present invention is directed to a fusion cage which has been designed to be implanted using principally a posterior approach to the vertebral bone structures.

In a first embodiment of the present invention, the fusion cage includes a cage body having a proximal end and a distal end, said distal end having a diameter which is larger than the diameter of the proximal end. The distal end further is rounded with for example a bull nose in order to facilitate the insertion of the cage body relative to one or more bone structures. The distal end could alternatively have a snub nose with or without a starter turn of a thread. The snub nose has a starter diameter that is smaller than the diameter of the distal end. The cage body is preferably conically-shaped. This shape is particularly advantageous due to the fact that the normal lordosis of the vertebral bone structures defines a wedged-shape space for a vertebral disk between, for example, lumbar vertebrae. Accordingly, the conically-shaped body cage can be sized and selected in order to maintain or enlarge upon the normal lordosis.

In a second embodiment of the present invention the cage body can include a cylindrically-shaped portion and a conically-shaped portion. The cylindrically-shaped portion is located adjacent to the distal end and the conically-shaped portion extends from the cylindrically-shaped portion and tapers toward the proximal end.

In a third embodiment of the present invention, a fusion cage includes a cage body having a proximal end and a distal end with the proximal end having a diameter which is smaller than the diameter of the distal end. The distal end has a flute formed therein. Additionally, the cage body has an outer surface and at least one flute formed in the outer surface. These flutes act as a relief much as the flute placed on self-tapping screws in order to facilitate the insertion of the fusion cage using a twisting motion between two vertebral bone structures.

In a fourth embodiment of the invention, a fusion cage includes a cage body having a proximal end and a distal end, the proximal end having a diameter which is smaller than the diameter of the distal end. The cage body has an outer surface and a thread formed as part of the outer surface. The thread aids the cage body in being inserted. As the cage is inserted, it gradually spreads apart the vertebral bone structures in order to regain or enlarge the natural lordosis of the adjacent vertebral bone structures. As with other embodiments of the present invention, flutes can be provided in the thread in order to allow for enhanced thread tapping by the cage and for a smoother insertion of the fusion cage between the vertebral bone structures. Preferably two or three flutes would be formed spaced about the fusion cage in order that one flute would be engaging with or adjacent to an upper vertebral bone structures with another flute

being engaging with or adjacent to a lower vertebral bone structure. Such a relationship maintains alignment of the fusion cage and prevent wandering as the fusion cage is introduced between the two vertebral bone structures. Without two or more flutes, wandering might occur due to the fact that the thread is only substantially engaged with the vertebral bone structures and not with the disk material between the vertebral bone structures, which disk material does not provide support to the thread.

In a further aspect of the invention, any of the above embodiments can be provided with a plurality of apertures through the fusion cage and an internal cavity with the apertures communicating between the internal cavity and the external surface of the fusion cage. Bone growth inducing substances, such as bone chips, can be packed into the internal cavity either before the fusion cage is inserted or after the fusion cage has reached a final insertion position, or packed in both before and after. The bone chips come in contact with the vertebral bone structures through the apertures in order to facilitate fusion between the adjacent vertebral bone structures.

In another aspect of the invention which can be included in any of the above embodiments, the cage body can have a round or bull nose distal end with one or more flutes formed in the round or bull nose distal end in order to enhance the self-tapping nature of the fusion cage and to prevent the cage from wandering.

In yet another aspect of the invention, introduction tools allow the fusion cage to be accurately positioned between the vertebral bone structures. A preferred introduction tool allows for the cage to be implanted and thereafter allows an end cap of the cage to be conveniently removed, if desired, in order to place bone growth inducing substances in the cage.

The method of the present invention affords access to adjacent vertebral bone structures using an posterior approach and procedure. Such posterior approach and procedure can be performed percutaneously using a minimally invasive technique with an introduction set including cannulas. Such a procedure is minimally invasive as the tissues can be spread using a set of cannula of increasing size and a small opening thereby developed through which a fusion cage can be inserted. Such a procedure is less traumatic to the tissue than an alternate posterior approach and procedure, also known as an posterior lumbar interbody fusion, where an incision is made, through the tissues. It is to be understood however that either posterior approach and procedure can be used with the fusion cage and fall within the scope of the invention.

After such access, using preferably a minimally invasive technique, degenerate disk material can be removed and, using a cannula and insertion tool, an appropriately shaped fusion cage can be screwed into place between the vertebral bone structures in order to stabilize the vertebral bone structures and allow for fusion. Either preparatory to insertion of the fusion cage or after it has been inserted, bone chips or other bone growth inducing substances can be inserted into the

fusion cage to promote bone to bone contact and subsequent fusion.

It is to be understood that although the above-embodiments have been described with respect to the fusion of adjacent vertebral bodies or bone structures, that the present invention can be used (1) to fuse together a variety of bone structures, in addition (2) to being fused to one bone structure and used as, for example, a base for an implant or (3) to being used to reunite the pieces of a broken bone.

Other objects and advantages of the invention can be obtained through a review of the specification and the figures.

Brief Description of the Figure

Anterior Fusion Cage:

Figure 1 is a partially sectional side view of an embodiment of the anterior fusion cage of the invention.

Figure 2 depicts a left end (distal end) view of the fusion cage of Figure 1.

Figure 3 depicts a right end (proximal end) view of the fusion cage of Figure 1.

Figure 4 depicts a view through line 4-4 of the fusion cage of Figure 1.

Figure 5 depicts the fusion cage of Figure 1 in conjunction with an introduction tool.

Figure 6 depicts an alternative embodiment of the introduction tool.

Figures 7, 8, and 9 depict progressive stages in the method of inserting the anterior fusion cage between adjacent vertebral bone structures.

Figure 10 depicts a side view of an alternative embodiment of the anterior fusion cage of the invention.

Figure 11 depicts the left end (distal end) view of the fusion cage of Figure 10.

Figure 12 depicts the right end (proximal end) view of the fusion cage of Figure 10.

Figure 13 depicts a side view of yet another embodiment of the anterior fusion cage of the present invention.

Figure 14 depicts a left distal end (distal end) view of the fusion cage of the invention of Figure 13.

Figure 15 depicts a right end (proximal end) view of the fusion cage of the invention of Figure 13.

Figure 16 depicts a sectional view taken through line 16-16 of Figure 13.

Posterior Fusion Cage:

Figure 17 is a partially sectional side view of an embodiment of the posterior fusion cage of the invention.

Figure 18 depicts a left end (distal end) view of the fusion cage of Figure 17.

Figure 19 depicts a right end (proximal end) view of the fusion cage of Figure 17.

Figure 20 depicts a view through line 20-20 of the fusion cage of Figure 17.

Figures 21, 22, and 23 depict progressive stages in the method of inserting the posterior fusion cage between adjacent vertebral bone structures using the cage depicted in Figure 25.

Figure 24 depicts a side view of an alternative embodiment of the posterior fusion cage of the invention.

Figure 25 depicts a side view of another embodiment of the posterior fusion cage of the invention.

Figure 26 depicts a left end (distal end) view of the embodiment of the fusion cage of Figure 25.

Figure 27 depicts the fusion cage of Figure 25 in conjunction with a new preferred insertion tool that can preferably be used with the anterior fusion cages of Figure 1, 10 and 13, and with the posterior fusion cages of Figure 17 and 25.

Figure 28 depicts an end view of the insertion tool of Figure 27 along line 28-28.

Figure 29 depicts a partially broken away view of the fusion cage and the insertion tool of Figure 27 connected together.

Figure 30 depicts a perspective view of the end of the insertion tool depicted in Figure 28.

Figure 31 depicts a partially sectional view of the handle of the insertion tool of Figure 27.

Detailed Description of the Preferred Embodiment

Anterior Fusion Cage:

With respect to the figures in a particular Figure 1, a side view of the preferred embodiment of the fusion cage 20 is depicted. Fusion cage 20 includes a fusion cage body 22 which in this preferred embodiment is provided in the shape of a cone. Fusion cage 20 includes a distal end 24 and a proximal end 26. The distal end 24 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 20 relative to one or more bone structures. The proximal end 26 includes an opening 28 which communicates with an internal cavity 30 defined by the fusion cage 20. The opening 28 in a preferred embodiment is threaded so that it can receive an end cap or plug 32 (Figure 5). End cap 32 is used to close off the proximal end 26 and retain bone growth inducing substances packed therein as described herein-below. As can be seen in Figure 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, square or hex-shaped section 35 which can be used with a socket wrench to tightly position end cap 32 in opening 28 and which can be engaged by a preferred insertion tool of Figure 27. Further the unthreaded portion of bore 34 could equally be cylindrical with an irregularity to allow for mating with an insertion tool, as well as having a variety of other shapes. The proximal end 26 further define first and second peripheral indentations 36, 38. These peripheral indentations 36, 38 receive tangs from an insertion tool as described hereinbelow for facilitating the insertion of the fusion cage 20.

A thread 40 is defined as part of the outer cylindrical surface 41 of the body 22. It is to be understood that the thread can be replaced with a plurality of discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

The rounded distal end 24, and at least some of the turns of thread 40 defined flutes or relief grooves 42, 44, and 46. (Figures 1, 2.) In a preferred embodiment, flutes 42, 44, and 46 meet at a central point 48 of the distal end 24 on the longitudinal axis 50 of the fusion cage 20. In other embodiments the flutes can be smaller and not extend all the way to the central point 48 on the longitudinal axis 50. Still in other embodiments, the flutes can be eliminated from the distal end 24 and such embodiments are still within the spirit and scope of the invention.

The flutes extend from the distal end 24 toward the proximal end 26 as shown in Figure 1 with respect to flute 42. These flutes are defined by the sections 52 which are removed from the thread. In a preferred embodiment, the flutes become narrower as they approach the proximal end 26 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several turns of the thread adjacent to the distal end and/or to just the distal end.

As can be seen in Figures 1, 4, a plurality of apertures 54 are provided through wall 56 of the fusion cage 20. In a preferred embodiment, these apertures 54 are formed by broaching grooves 58 in the internal surface 60 of the internal cavity 30. The effect of such broaching is to remove material from the valleys between the turns of the thread 40, thus defining the aperture 54. The advantages of such an arrangement are taught by the above-referenced U.S. Patent No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone structures and the bone packed within the internal cavity 30 of the fusion cage 20.

The apertures 54 in a preferred embodiment increase in size from smaller apertures closer to the distal end 24 to a larger aperture closer to the proximal end 26. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in Figure 1, all the apertures are of the same size.

As can be seen in Figure 4, the apertures are clustered about a transverse axis 51, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (Figure 9) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral section of the fusion cage found along the other transverse access 53 do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process.

A preferred embodiment of the conically-shaped fusion cage 20 includes a fusion cage which is 23 mil-

limeters in length having a distal end 24 with a diameter of 14 millimeters and a proximal end 26 with a diameter of 18 millimeters. The cage body is a right circular cone. The thread has a pitch of 30° and there are ten turns per inch with a thread depth of .053 inches. Further the cage is made of a titanium metal or alloy such as Ti64. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding, casting, or sintering can be used to accomplished formation of the fusion cages.

The cage is inserted between vertebral bodies using an insertion tool 62 (Figure 5). Insertion tool 62 includes an inner handle 64 and an outer handle 66. The outer handle includes a bore 68 for receiving the inner handle 64. Handles 64, 66 include knobs 70, 72 respectively. The distal end of inner handle 64 defines a threaded shaft 74, having a reverse thread to facilitate easy removal, and the distal end of handle 66 define a cylindrical disk 76 which has first and second tangs 78, 80, projecting from the peripheral edge of the cylindrical disk 76. These tangs 78, 80 are designed to mate with the peripheral indentation 36, 38 of the fusion cage 20. For purposes of inserting the fusion cage between the vertebral bodies, the end cap 32 is inserted into the fusion cage 20 as shown in Figure 5. Then the threaded shaft 74 of the inner handle is introduced into the threaded bore 34 of the end cap 32. After this is accomplished, the outer handle 66 is slid over the inner handle 64 and the tangs 78, 80 are positioned into engagement with the indentations 36, 38. In this arrangement, the fusion cage 20 can be anteriorly inserted into the space between the vertebral body structure using the insertion tool 62.

An alternative embodiment of the insertion tool is shown in Figure 6. In this figure, insertion tool 82 includes a handle 84 with a knob 86. At the end of the insertion tool 82 distal from the knob 86 is a cylindrical disk 88 which has first and second tangs 90, 92, which have the same function as the above tangs 78, 80. Extending from the center of the cylindrical disk 88 along the centerline of the insertion tool 82 is a shaft 94 which has a ball detent 96. For use with insertion tool 82, the threaded bore 34 of the end cap 32 would be replaced with a bore having a lip which could engage with the ball detent 96 of the insertion tool 82.

It is to be understood that the insertion tool depicted in Figure 27 and described below is preferable to the above described insertion tools for both the anterior fusion cages and the below described posterior fusion cages.

The method for inserting the fusion cage 20 of Figure 1 using an anterior approach and procedure to the vertebral bodies is as follows. It is to be understood that although the focus of this discussion is on a laparoscopic procedure, that the anterior approach and procedure can also include a more invasive procedure where a long incision is made in the abdomen wall.

With an anterior approach, using an introduction set such as described by way of example only, in U.S. Patent 4,863,430, entitled "INTRODUCTION SET WITH FLEX-

IBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. With the same or a larger diameter cannula, the fusion cage 20 can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap 32 is affixed to the fusion cage 20. Insertion tool 62 is then secured to the fusion cage 20 and the fusion cage is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in Figures 7, 8, 9, by upper body 98 and lower body 100. In the initial position as shown in Figure 7, the fusion cage 20 is adjacent to the anterior surfaces 102, 104 of the vertebral bodies 98, 100. As the introduction tool is turned, the thread 40 of the fusion cage 20 bites into the vertebral bodies 98, 100. Further turning of the introduction tool causes the fusion cage to move through the position shown in Figure 8 to the final resting position shown in Figure 9, where the distal end 24 is moved adjacent to the posterior sections 106, 108 of the vertebral bone structures 98, 100. As this occurs, the fusion cage 20 increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies and causing the vertebral bodies to pivot about the posterior sections 106, 108, with such posterior sections acting like a hinge. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distractions also occur at the posterior sections where the hinged effect is exhibited. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of the anatomy holding the vertebral bodies in place.

Once the fusion cage 20 is appropriately positioned, the handle 64 of the insertion tool 62 is unscrewed from the cap 32 and the fusion handle 62 is pulled away from the fusion cage.

An alternative embodiment of a fusion cage 200 is shown in Figures 10, 11, and 12. Fusion cage 200 includes a distal end 202 and an a proximal end 204. Fusion cage 200 includes an internal cavity 206. End caps not shown can be used to close the ports 208, 210 of distal and proximal ends 202, 204. A thread 212 is defined on the external conical surface 214 of the fusion cage 200. Defined by the thread 212 are first and second flutes 216, 218, which in this embodiment extend from the distal end 202 to the proximal end 204. These flutes provide thread relief allowing the fusion cage 200 to be self-tapping.

The fusion cage 200 includes a plurality of elongated apertures 220 which are formed through the side walls of a fusion cage 200. The elongated apertures 202 are formed in such a way that the internal conical surface

214 is spaced away from the internal surface 224 of the internal cavity 206 by the thickness of the sidewall 222.

A further embodiment of the invention is shown in Figures 13, 14, 15 and 16. In Figure 16 the fusion cage 300 has distal and proximal ends 302 and 304 respectively. The fusion cage 300 defines an internal cavity 306, and ports 308 and 310 defined through the distal and proximal ends 302 and 304 respectively. A thread 312 is defined as part of the external conical surface 314 of the fusion cage 200. First, second and third flutes 316, 318, and 320, are defined in the thread 312 from the distal end 302 to the proximal end 304. These flutes give the fusion cage 300 an enhanced self-tapping advantage. These flutes are equally spaced about the fusion cage 300 in a manner similar to the flutes of the fusion cage embodiment 20 in Figure 1.

A plurality of aperture 322 is provided through the external conical surface 314 of the fusion cage 300 and through the side wall 324 opening into the internal cavity 306. Accordingly, at the location of the aperture 322 the external surface 314 is held away from the internal surface 326 by the thickness of the side wall 324.

Posterior Fusion Cage:

With respect to the figures in a particular Figure 17, a side view of the preferred embodiment of the posterior fusion cage 420 is depicted. Fusion cage 420 includes a fusion cage body 422 which in this preferred embodiment is provided with a conically-shaped portion 423 and a cylindrically-shaped portion 425. It is to be understood that alternatively the entire body 422 can be conically-shaped. Further, as appropriate the shape of the cage body 422 can be more complex with various conical and/or cylindrical configurations. Fusion cage 420 includes a distal end 424 and a proximal end 426. The distal end 424 in a preferred embodiment is rounded or bull nosed in order to facilitate the insertion of the fusion cage 420 relative to one or more bone structures. The proximal end 426 includes an opening 428 (Figure 19) which communicates with an internal cavity 430 (Figure 20) defined by the fusion cage 420. The opening 428 in a preferred embodiment is threaded so that it can receive an end cap or plug such as 32 of the embodiment in Figure 5. End cap is used to close off the proximal end 426 and retain bone growth inducing substances, such as bone chips, packed therein as described herein-below. As can be seen in the embodiment of Figure 5, end cap 32 includes a threaded bore 34 which is designed to receive an insertion tool. The threaded bore 34 has an initial unthreaded, square or hex-shaped portion 35 which can be used with a socket wrench to tightly position end cap 32 in opening 428 and which can also be engaged by the insertion tool of Figure 27 described below. Portion 35 can be otherwise shaped as described above.

The proximal end 426 of the embodiment of Figure 19 further define first and second peripheral indentations 436, 438 which are centered about transverse axis 453.

These peripheral indentations 436, 438 receive tangs from an insertion tool as described below for facilitating the insertion of the fusion cage 420. These indentations are also used to line up the cage 420 for proper insertion between the vertebral bodies as discussed below.

A thread 440 is defined as part of the outer cylindrical surface 441 of the body 422. It is to be understood that the thread can be replaced with a plurality of interrupted or discrete threads or a plurality of projections, ridges, protrusions, barbs, or spurs and be within the spirit and scope of the invention.

The rounded distal end 424, and at least some of the turns of thread 440 can in a preferred embodiment can define flutes or relief grooves 442, 444, and 446 (Figures 24, 25). It is to be understood that in alternative embodiments the flutes can be eliminated from the distal end 424 and the thread 440, since for example, the bore for the insertion of the fusion cage 420 between the vertebral bodies can be pre-tapped. Still in alternative embodiment, the flutes on the distal end can remain to assist in the insertion of the cage 420 between the vertebral bodies. In a preferred embodiment, flutes 442, 444, and 446 meet at a central point 448 of the distal end 424 on the longitudinal axis 450 of the fusion cage 420. In other embodiments the flutes can be smaller and not extend all the way to the central point 448 on the longitudinal axis 450. Still as indicated above in other embodiments, the flutes can be eliminated from the distal end 424 and the thread 440 and such embodiments are still within the spirit and scope of the invention.

The flutes can extend from the distal end 424 toward the proximal end 426 as shown in the alternative embodiment in Figure 24 with respect to flute 542. These flutes are defined by the sections 552 which are removed from the thread. In this embodiment, the flutes become narrower as they approach the proximal end 526 due to the fact that thread relief for purposes of self-tapping becomes less important as the cage reaches a final resting position. As shown in other embodiments, the flutes can be deeper and extend from the distal end completely to the proximal end. Still further in other embodiments the flutes can be confined to the first several turns of the thread adjacent to the distal end and/or to just the distal end.

With respect to Figures 17, 20, a plurality of apertures 454 are provided through wall 456 of the fusion cage 420. In a preferred embodiment, these apertures 454 are formed by broaching grooves 458 in the internal surface 460 of the internal cavity 430. The effect of such broaching is to remove material from the valleys between the turns of the thread 440, thus defining the aperture 454. The advantages of such an arrangement are taught by the above-referenced U.S. Patent No. 4,961,740, which patent is incorporated herein by reference and allows for immediate bone to bone contact between the vertebral bodies or bone structures and the bone packed within the internal cavity 430 of the fusion cage 420.

The apertures 454 in a preferred embodiment increase in size from smaller apertures closer to the

proximal end 426 to a larger aperture closer to the distal end 424. This increase in size allows for more bone to bone contact. Alternatively in the embodiment as shown in Figure 17, all the apertures are of the same size.

As can be seen in Figure 20, the apertures are clustered about a transverse axis 451, both at the upper and lower end of the axis. This is so that in position, the apertures come into contact with the upper and lower vertebral bone structures (Figure 23) to encourage bone growth through the fusion cage from the vertebral bone structures. The lateral sections of the fusion cage found along the other transverse axis 453 do not have apertures in order to prevent growth of disk material which might interfere with the bone fusing process. As can be seen viewing both Figures 19 and 20 together, the indentation 436 and 438 are centered on the axis 453 with the aperture 454 centered on axis 451. Axis 451 is preferably perpendicular to axis 453. The insertion tool has tangs that are inserted in indentation 436 and 438. Accordingly, the position of the insertion tool defines the position of the apertures 454 in that upon insertion the apertures 454 can be put in contact with the upper and lower vertebral bodies to allow bone ingrowth and prevent lateral growth of disk material.

A preferred embodiment of the conically-shaped fusion cage 420 includes a fusion cage which is 28 millimeters in length having a distal end 424 with a diameter of 16 millimeters and a proximal end 426 with a diameter of 14 millimeters. The cage body is a right cylinder from the distal end 424 extending toward the proximal end 426 for four turns of thread 440. Then the cage 420 becomes a right cone from the remaining five turns of thread 440 until thread 440 terminates at proximal end 426. This conically-shaped portion is defined by relief 455 of 3.2°. The thread has a pitch of 30° and there are ten turns per inch with a thread depth of .053 inches. Further the cage is made of a titanium metal or alloy such as Ti64. Preferably this and the other disclosed fusion cages disclosed are machined. However, the processes such as molding, casting or sintering can be used to accomplished formation of the fusion cages.

The cage is inserted between vertebral bodies using a preferred insertion tool 700 shown in Figure 27. Insertion tool 700 includes a handle 702 with an outer shaft 704 extending therefrom. The handle 702 includes first and second wings 706, 708 which make the handle easier to grab. The outer shank 704 is hollow and disposed within the outer shaft is an intermediate shaft 710 which can be seen extending from the cage engaging in 712 of the shaft 704. The cage engaging end 712 includes first and second tangs 714, 716 which can be inserted in the indentation of the cage such as for example indentations 436, 438, as shown in Figure 19, and indentations 636 and 638 shown in Figure 27. The end of shaft 710 includes a square-shaped drive 718 which engages the square-shaped unthreaded portion of the otherwise threaded bore such as bore 34 of an end cap such as end cap 32 as shown in Figure 5. This same end cap can be used in the end of fusion cage 620. Alternatively, the

square drive can be hexagonal shape with the unthreaded portion of the bore 34 being hexagonal shaped to provide the necessary mating arrangement. Other mating shapes can also be used. A first knurled knob 720 is secured to intermediate shaft 710 in order to provide a mechanism for rotating intermediate shaft 710 inside of outer shank 704. As can be seen in Figure 31, the intermediate shank 710 is spring biased relative to the handle 702 with a spring 722. Spring 722 is imbedded in a bore 724 of handle 702. In Figure 31, the first knurled knob 720 and the shank 710 are pulled back and thus compress the spring 722. In Figure 27, the first knurled knob 720 is released and the spring (not shown) is uncompressed.

An inner shaft 726 is located within a bore 728 of the intermediate shaft 710. The inner shaft 726 ends in a threaded portion 730 (Figure 30). The other end of inner shaft 726 is secured to the second knurled knob 732. Inner shaft 726 is free to rotate, through the use of the second knurled knob 72, within the bore 728 of the intermediate shaft 710. In addition the inner shaft 728 has limited freedom of motion along the longitudinal axis of the inner shaft 726.

The operation of the insertion tool 700 is as follows. With the insertion tool 700 not secured to a fusion cage, the insertion tool is as depicted in Figure 27 with the threaded portion 730 being either received entirely within bore 728 or extending a minimal amount out of bore 728. With the end cap secured in the fusion cage, the exposed square drive 718 is mated with the square portion of the bore in the end cap. The tangs 712, 714 are aligned with the indentations 636 and 638 and the tool is pushed in so that the tang 712, 714 are received in the indentations 636, 638. As this occurs, the knurled knob 730 moves up to the position as shown in Figure 29 and 31, compressing the spring. After this occurs, the second knurled knob 732 can be turned clockwise in order to engage the threaded portion 730 of the inner shaft 726 with the threaded portion of the bore of the end cap. This draws the fusion cage securely to the insertion tool 700 as shown in Figure 29. In this position, the cage is ready for insertion between the vertebral bodies. The handle 702 is then used to screw the cage between the vertebral bodies into the final resting position. Once the cage is in the final resting position, second knurled knob 732 is turned counter-clockwise in order to back the threaded 730 out of the threaded portion of the bore of the end cap. As this occurs, the spring 722 causes the square drive 718 to push against the end cap maintaining the end cap in its position relative to the fusion cage until the threaded portion 730 disengages itself from the threaded portion of the end cap, and the insertion tool 700 is disengaged from the fusion cage and can be removed. Thus the square drive, which is spring loaded, prevents the end cap on the cage from screwing out when the insertion tool is removed from the cage.

Should it be desired to move the end cap with the fusion cage in place, the square drive 718 can be inserted into the square portion of the threaded bore.

The threaded portion 730 of the inner shaft 726 can then be screwed into engagement with the threaded portion of the threaded bore of the end cap, preferably with the tangs unaligned with the indentations. The first knurled knob 720 can then be turned in order to back the cap out of the fusion cage. A reverse of this operation can be used to insert the end cap into the fusion cage after additional bone growth inducing substances are packed into the fusion cage.

The method for inserting the fusion cage 420 of Figure 17 using a posterior approach and procedure to the vertebral bodies is as follows. Both a minimally invasive procedure and a more invasive procedure where a long incision is made in the back can be used.

With a posterior approach, using an introduction set such as described by way of example only, in U.S. Patent 4,863,430, entitled "INTRODUCTION SET WITH FLEXIBLE TROCAR WITH CURVED CANNULA," which is incorporated by reference, but however with larger diameter instruments, an amount of disk material is removed between the two vertebral bodies or bone structures which are to be fused together. This procedure is accomplished through a cannula position adjacent to the vertebral bone structures. Then if required a thread is tapped in the upper and lower vertebral bodies. With the same or a larger diameter cannula, the fusion cage 420, or alternatively the preferred fusion cage 620 of Figure 25, can be introduced adjacent to the vertebral bone structures. In a first procedure, the fusion cage is packed with bone growth substances and the end cap is affixed to the fusion cage 620. Insertion tool 700 is then secured to the fusion cage 620 and the fusion cage is guided through the cannula to a location adjacent to the upper and lower vertebral body such as presented schematically in Figures 21, 22, 23, by upper body 498 and lower body 500. In the initial position as shown in Figure 21, the fusion cage 620 is adjacent to the posterior sections 502, 504 of the vertebral bodies 498, 500. As the introduction tool is turned, the thread 640 (Figure 25) of the fusion cage 620 bites into the vertebral bodies 498, 500. Further turning of the introduction tool causes the fusion cage to move through the position shown in Figure 22 to the final resting position shown in Figure 23, where the distal end 624 is moved adjacent to the anterior sections 506, 508 of the vertebral bone structures 498, 500. As this occurs, the fusion cage 620 increases the lordosis or spacing between the vertebral bodies, basically distracting the vertebral bodies. It is noted that most of the distraction occurs adjacent to the anterior sections, but that distraction also occur at the posterior sections. Preferably, the lordosis is increased over the normal lordosis in order to stabilize the vertebral bone structures prior to fusion occurring. Stabilization occurs due to the fact that increased lordosis places additional stress on the anterior longitudinal ligaments which are part of the anatomy holding the vertebral bodies in place.

Once the fusion cage 620 is appropriately positioned, the insertion tool 700 is unscrewed from the cap

and the insertion tool 700 is pulled away from the fusion cage.

It is to be understood that the cage can be implanted without the use of a cannula by making a larger incision in the back. With this arrangement the bone chips would more often be packed into the cage after the cage reaches its final position and then an end cap would be secured to the cage. In the final position apertures 454 or 654 (embodiment of Figure 25) would be positioned adjacent vertebral bodies 498 and 500. No matter which procedure is used to insert the cage 420 or 620, it is advantageous to provide a bore between the vertebral bodies that is less than the diameter of the distal end 424. Thus, for a cage 420 or a cage 620 with a distal end having an 18 diameter, the bore would be 14 millimeters. Inserting the cage 420 or the cage 620 would cause the vertebral bodies to be distracted (Figure 22) and then rock back (Figure 23) onto the conically-shaped portion of the fusion cage 420.

An alternative embodiment of a fusion cage 520 is shown in Figures 24. Fusion cage 520 includes a distal end 524 and an a proximal end 526. A thread 540 is defined on the external surface of the fusion cage 520. Defined by the thread 540 are flutes 542, 544, 546, which in this embodiment extend from the distal end 524 toward the proximal end 526. These flutes provide thread relief 552 allowing the fusion cage 520 to be self-tapping.

Still an alternative and preferred embodiment of the invention as mentioned above is shown in Figure 25. In this embodiment the fusion cage 620 includes a blunt or flat distal end 624 and a proximal end 626. As in the other embodiments, the fusion cage is conically-shaped, and includes a thread 640 and aperture 654.

Figure 26 includes a view of the distal end 624 of the fusion cage 620. This distal end 624 uses a snub nosed portion that is closed. The diameter of the snub nosed portion 660 is smaller than the largest root of the thread 640 at the distal end 624. As can be seen in Figure 26, the thread 640 has a starter portion or starter turn 641 which includes approximately the first half turn of the thread 640. The diameter of the starter portion 641, as can be seen Figure 26, is substantially less than the outside diameter of the four turns of thread 640 which comprised the cylindrical portion 625. From the cylindrical portion 625, the cage 620 and the thread 640 taper off to the proximal end 626 and define the conically-shaped portion 623.

The starter turn 641 of thread 640, as the name implies, assist in promoting the proper engagement of the thread 640 with the upper and lower vertebral bodies. In this embodiment, as in prior embodiments, the distal end has a diameter of approximately 16 millimeters. The diameter of the snub nosed portion 660 is about 10 millimeters.

Industrial Applicability

The present invention affords the advantages of a fusion cage which can be introduced through a posterior

approach in order to maintain or increase lordosis between adjacent vertebral bodies. The fusion cage has the advantage of being conically-shaped and self-taping through the use of external flutes. The flutes additionally assist in keeping the fusion cage aligned and centered as the cage is being inserted between the vertebral bone structures.

Other advantages, aspects, and objects of the invention can be obtained through a review of the claims and the appended figures.

Additional embodiments of the invention can be constructed and fall within the scope of the claims.

Claims

1. A fusion cage for promoting fusion with one or more bone structures comprising:
 - a cage body having a proximal end and a distal end, said proximal end having a diameter which is smaller than a diameter of said distal end; and
 - said distal end being rounded in order to facilitate insertion relative to one or more bone structures.
2. A fusion cage for promoting fusion with one or more bone structures comprising:
 - a cage body having a proximal end and a distal end, said proximal end having a diameter which is smaller than a diameter of said distal end; and
 - said cage body having an outer surface and at least one flute formed in the outer surface.
3. A fusion cage for promoting fusion with one or more bone structures comprising:
 - a cage body having a proximal end and a distal end, said proximal end having a diameter which is smaller than a diameter of said distal end; and
 - said cage body having a outer surface and a thread formed into said outer surface.
4. The fusion cage of claims 1, 2 or 3 wherein:
 - said cage has a cylindrically-shaped portion located adjacent to the distal end and a conically-shaped portion located adjacent to the proximal end.
5. The fusion cage of claim 4 wherein:
 - a thread is defined by the cylindrically-shaped portion and the conically-shaped portion.
6. The fusion cage of any of the preceding claims wherein:
 - said cage body has a thread formed on an outer surface and at least one flute formed in the thread.
7. The fusion cage of claim 6 wherein the flute is formed in the distal end in order to facilitate the insertion of the fusion cage in the one or more bone structures, the flute extending from the distal end toward the proximal end.
8. The fusion cage of any of the preceding claims including:
 - at least three flutes formed in the outer surface being equally spaced about said distal end.
9. The fusion cage of any of preceding claims wherein:
 - said cage body has an outer surface and an internal cavity; and
 - a plurality of apertures are formed through the cage body which communicate said outer surface with said internal cavity.
10. The fusion cage of any of the preceding claims wherein said cage body is a right circular cone.
11. The fusion cage of any of the preceding claims further comprising a thread with a plurality of turns found on the outer surface, and the flute is formed in at least one of said turns.
12. The fusion cage of any of the preceding claims in combination with an insertion tool, said fusion cage including:
 - said proximal end having an opening which communicates with an internal cavity;
 - an end cap which can fit into said opening in order to close off said internal cavity;
 - said proximal end including at least one insertion tool receiving indentation;
 - said end cap including an insertion tool receiving threaded bore with an unthreaded portion with an irregularity; and
 - said insertion tool including:
 - a tang for being received in said indentation and a threaded shaft for being received in said threaded bore, and a shaft for mating with the unthreaded portion, said insertion tool for being engaged with said fusion cage for inserting said fusion cage relative to the one or more bone structures.
13. The fusion cage of claim 9 including:
 - said apertures increase in size from the distal end toward the proximal end.
14. A fusion cage for promoting fusion with one or more bone structures comprising:
 - a cage body having a proximal end and a distal end;
 - said cage body having a longitudinal axis, and a first transverse axis which is perpendicular to the longitudinal axis and a second transverse axis which is perpendicular to both the longitudinal axis and the first transverse axis;
 - a position indicator located at said proximal end, which position indicator is located along the first

transverse axis; and

said cage body having a plurality of apertures for promoting bone growth into the cage body, which apertures are located only substantially along the second transverse axis between the proximal end and the distal end. 5

15. The fusion cage of claim 14 wherein:

said position indicator includes an indentation into said proximal end. 10

16. The fusion cage of claim 15 wherein:

said distal end has a snub nose extending therefrom in order to facilitate insertion relative to one or more bone structures the snub nose having a diameter which is less than the diameter of the distal end. 15

17. The fusion cage of claims 14, 15 or 16 wherein:

the cage body includes a thread which has a starter turn located at the distal end, the starter turn of the thread extends from the snub nose in order to facilitate insertion relative to the one or more bone structures. 20

25

18. A fusion cage in combination with an insertion tool comprising:

said fusion cage having a cage body with a distal end and a proximal end, said proximal end including at least one insertion tool receiving indentation; 30

said proximal end including an insertion tool receiving threaded bore having an unthreaded portion with at least one irregularity; and

said insertion tool having a first shaft with a tang that can be received in said indentation, a second shaft with a portion which can mate with the unthreaded portion of the bore with the irregularity, and a third shaft with a threaded portion which can mate with the threaded bore. 35 40

19. The fusion cage and insertion tool combination of claim 18 wherein:

said second and said third shafts can rotate relative to the first shaft and relative to each other. 45

20. The fusion cage and insertion tool combination of claim 19 wherein:

one of said second and third shafts is biased relative to the other of said second and third shafts. 50

21. The fusion cage and insertion tool combination of claim 20 wherein:

said fusion cage includes an end cap which in part comprises said proximal end, and wherein said end cap includes said threaded bore, and wherein said end cap can be selectively removed from the remainder of the proximal end. 55

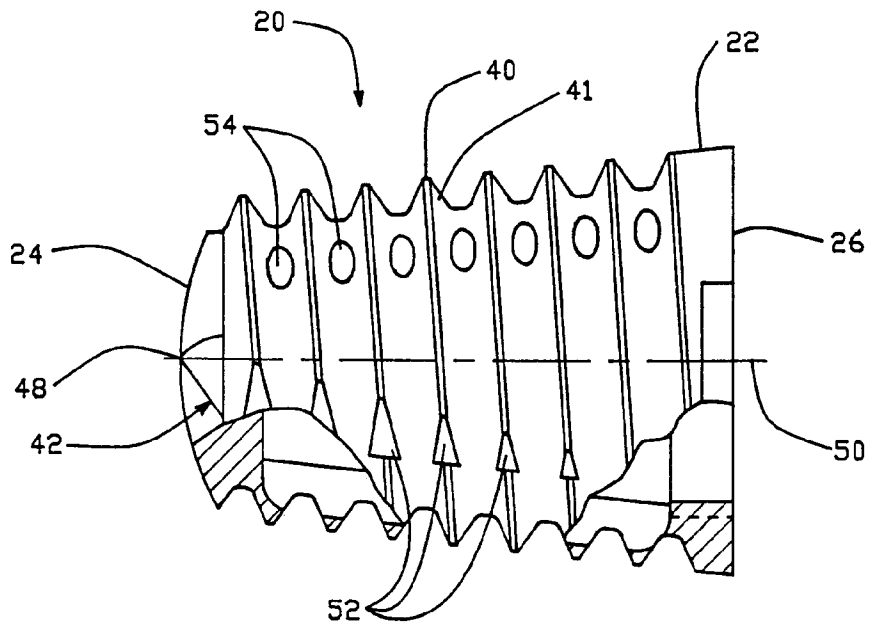


FIG. - 1

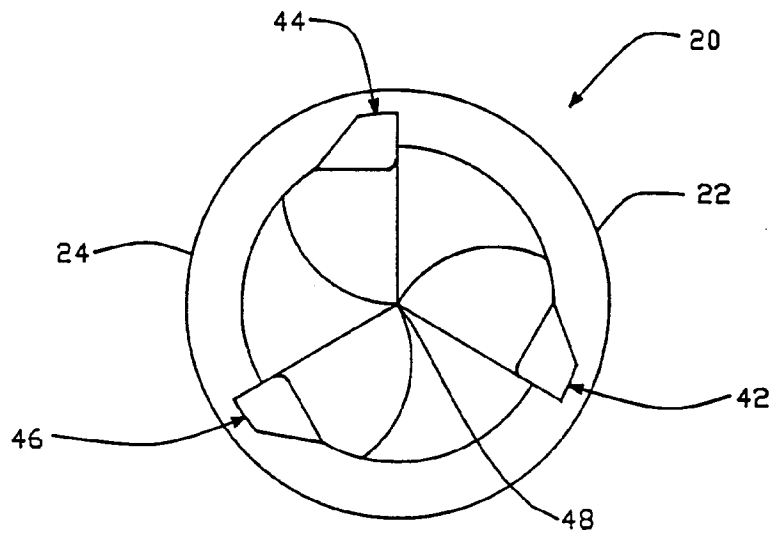


FIG. - 2

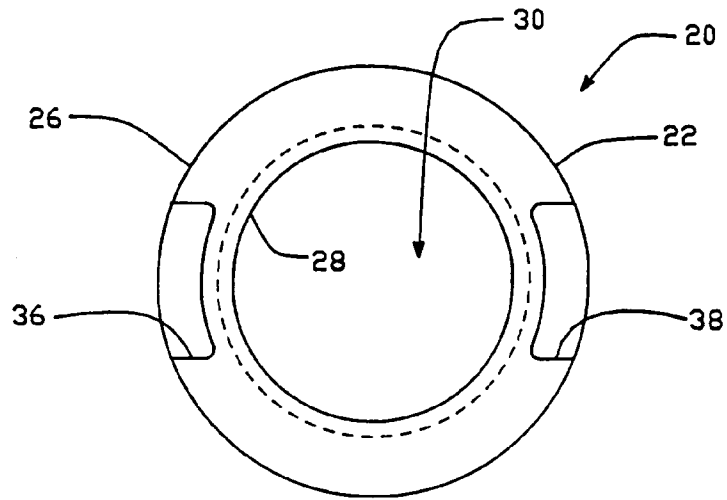


FIG. -3

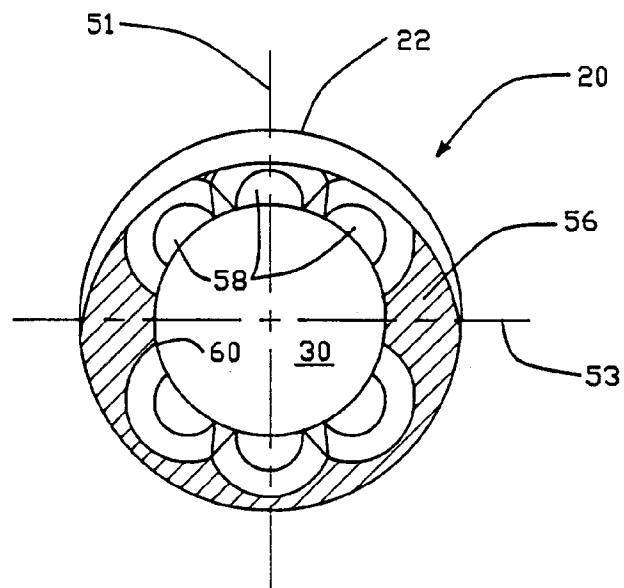


FIG. -4

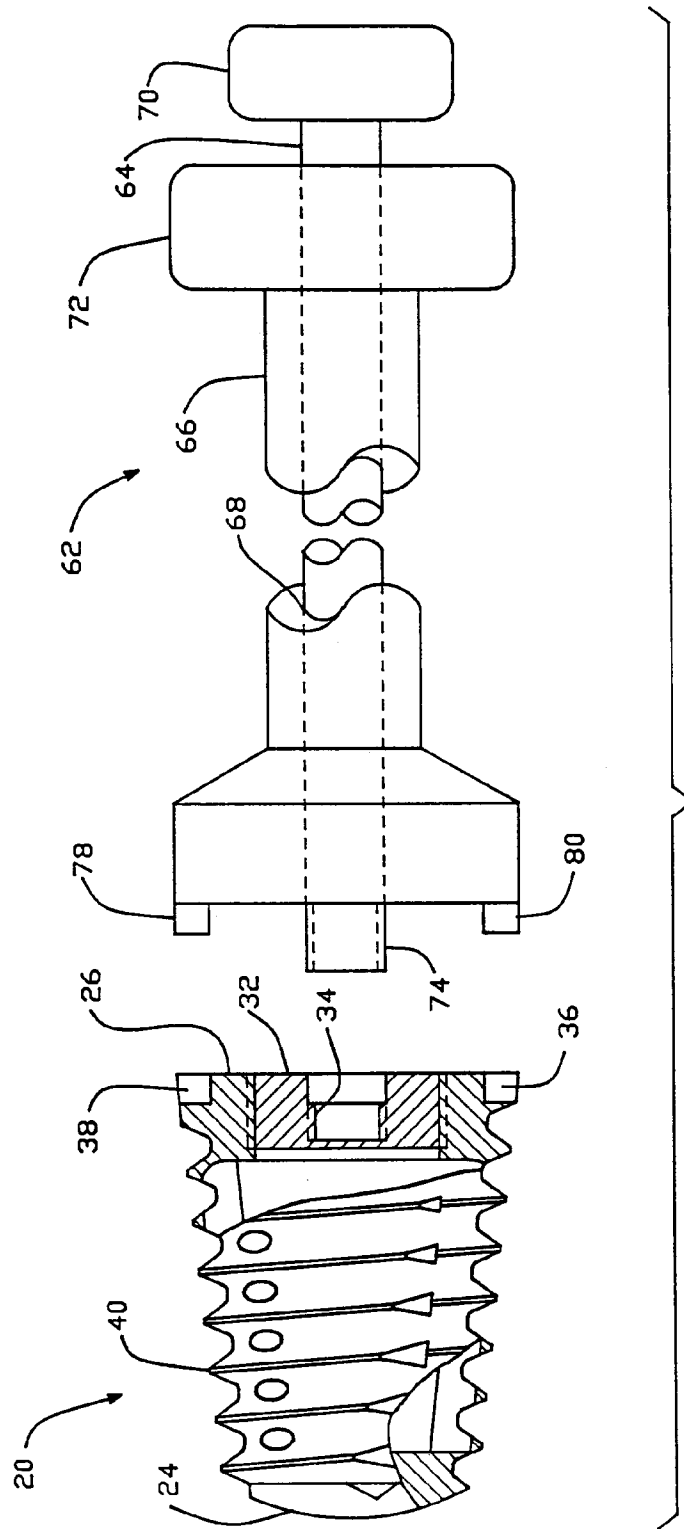


FIG. -5

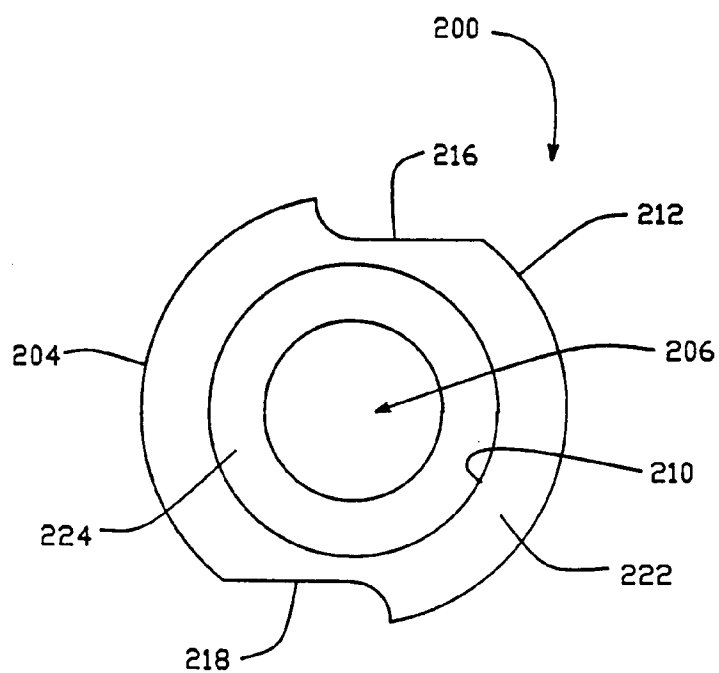


FIG. - 12

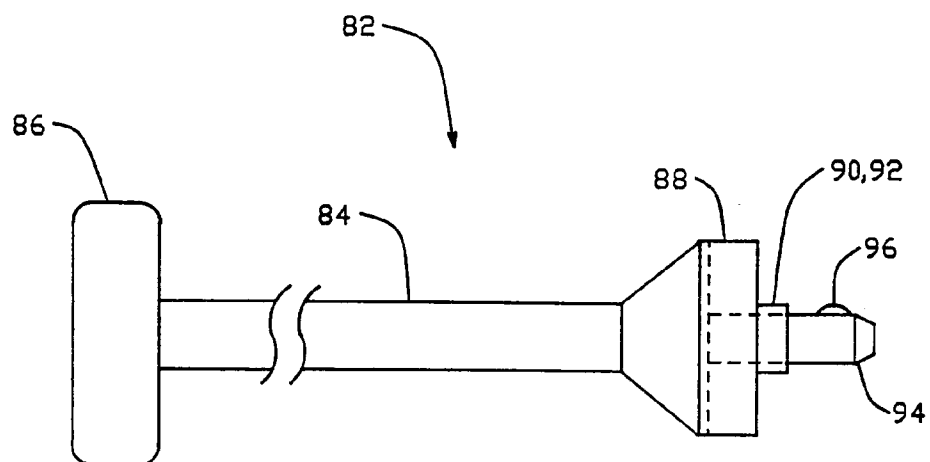


FIG. - 6

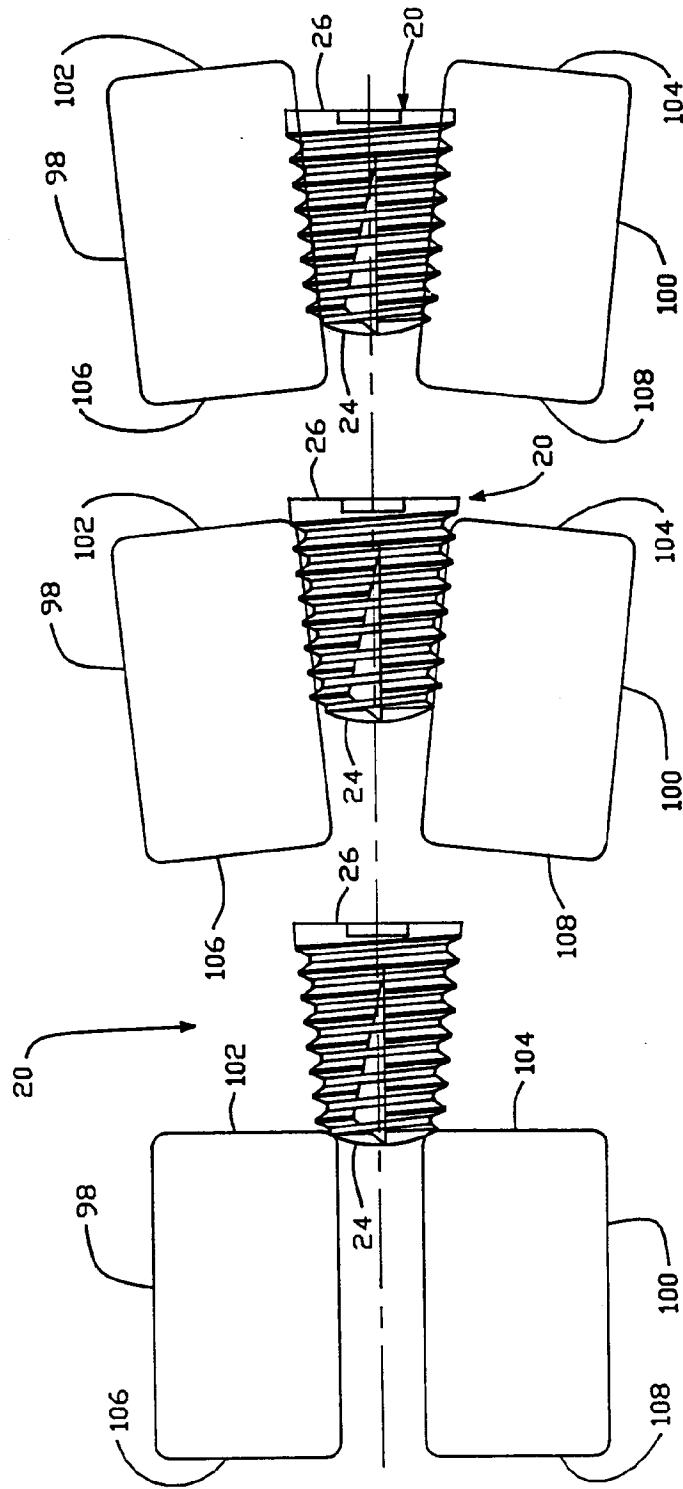


FIG.—9

FIG.—8

FIG.—7

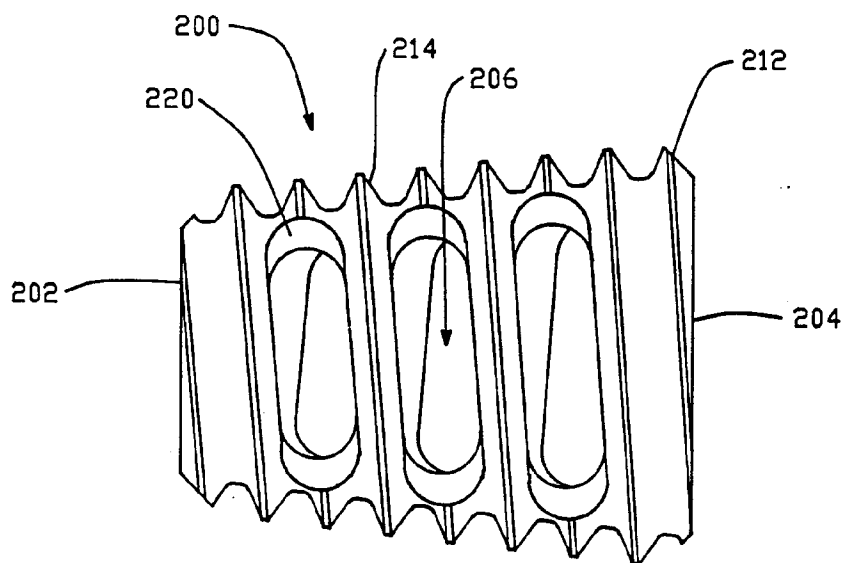


FIG. - 10

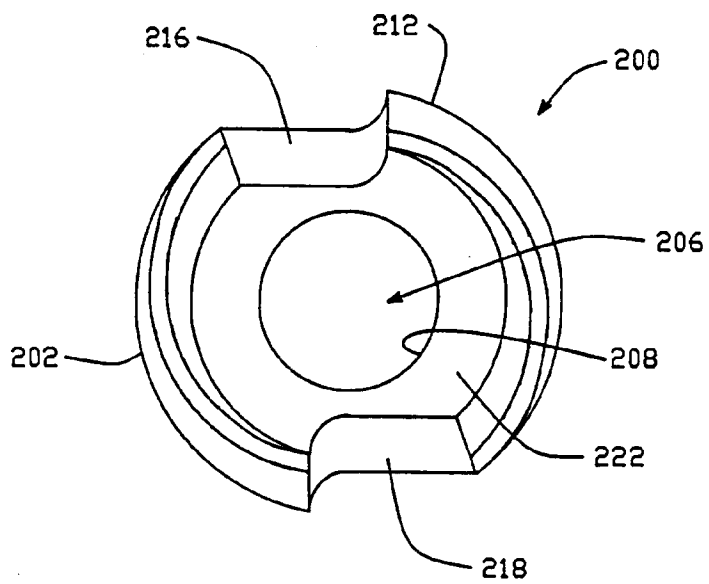


FIG. - 11

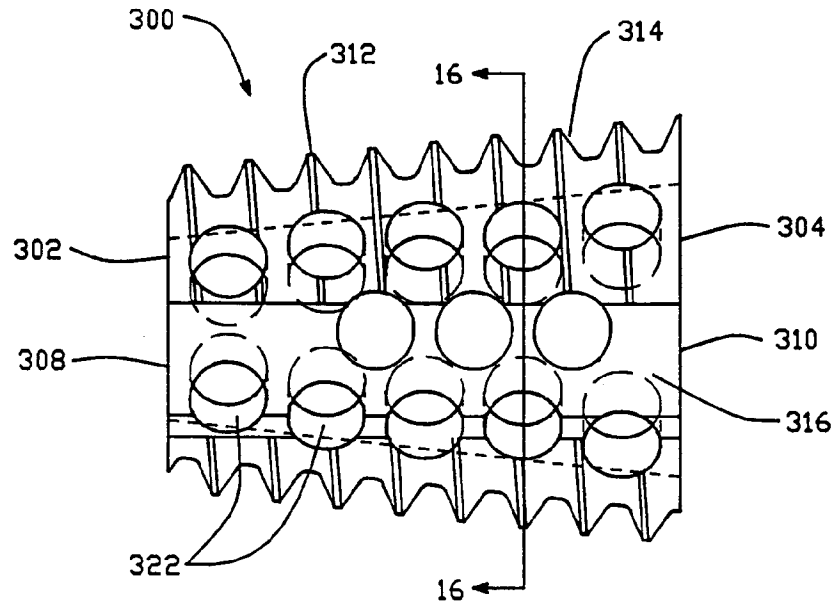


FIG.-13

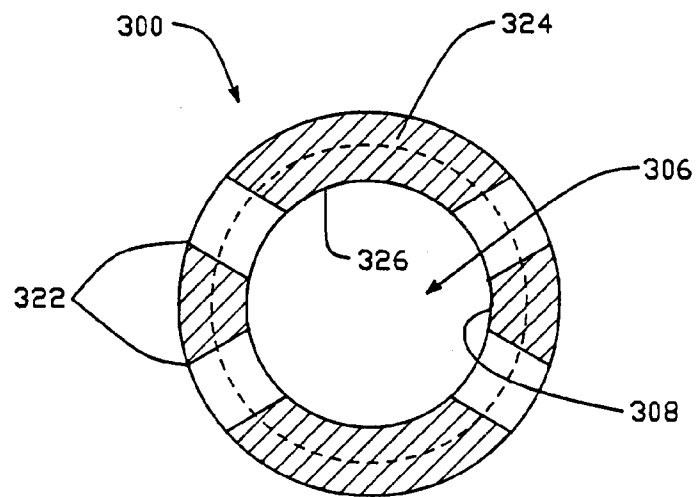


FIG.-16

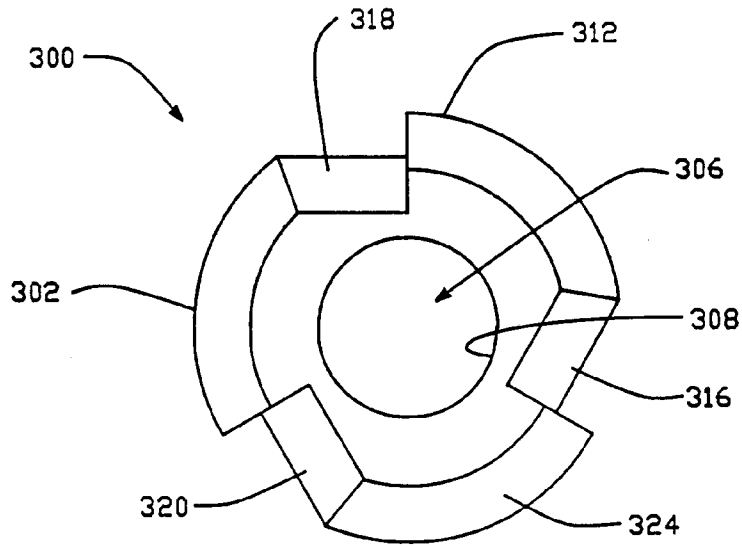


FIG.-14

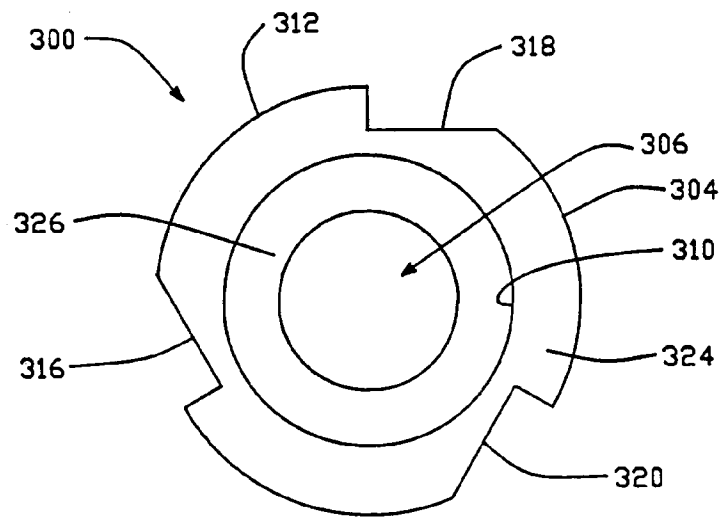


FIG.-15

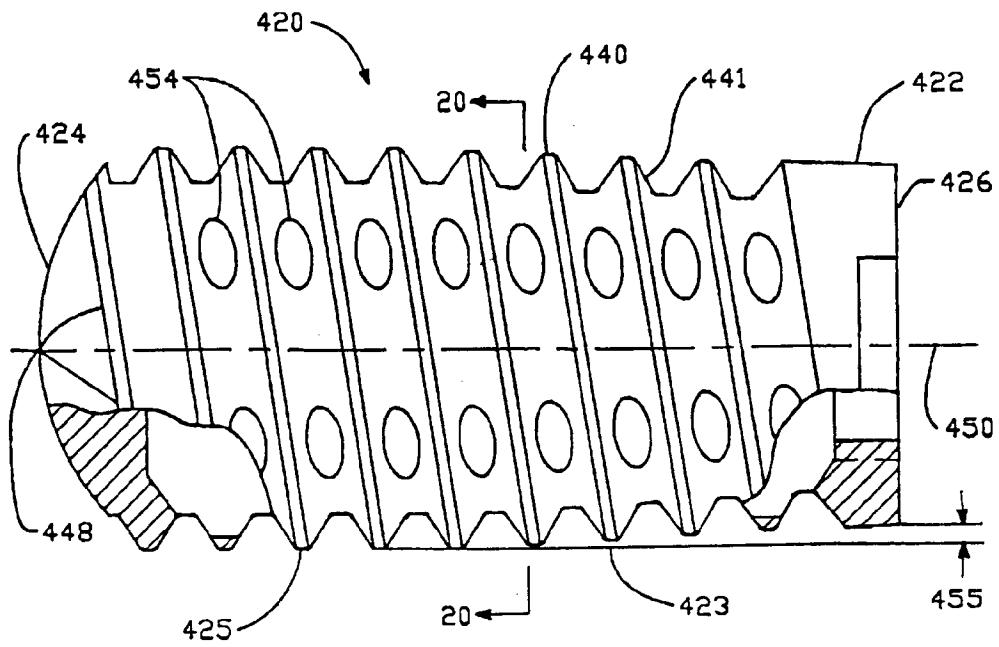


FIG.-17

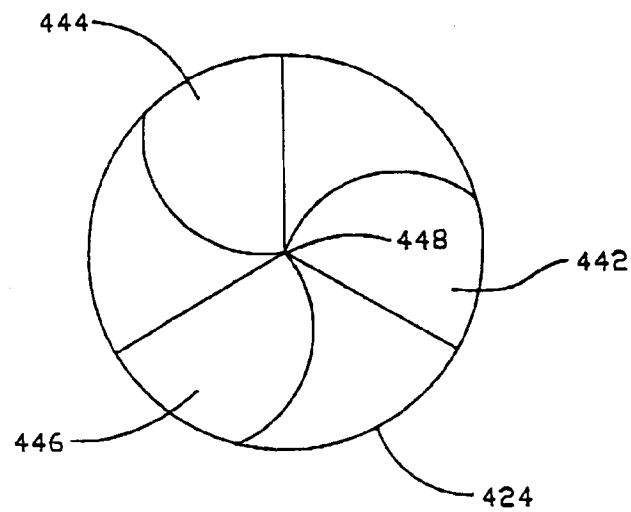


FIG.-18

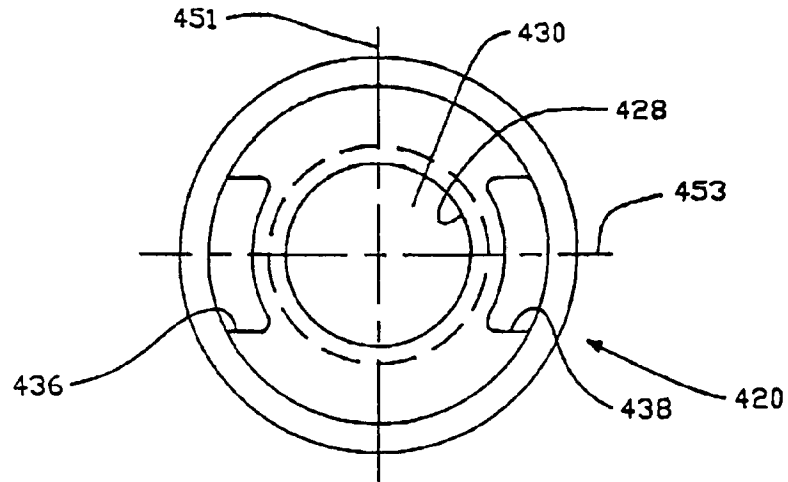


FIG. - 19

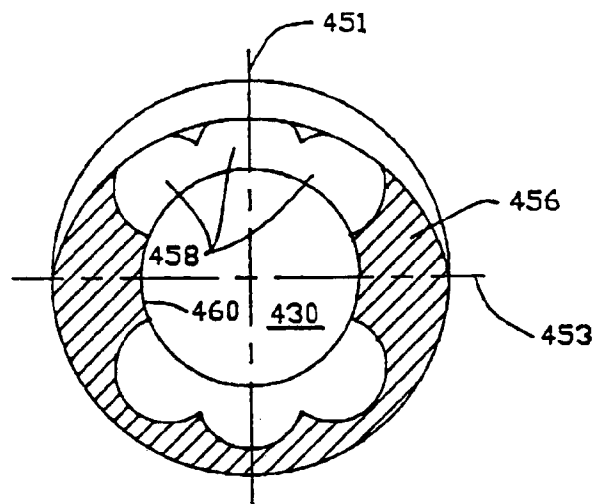


FIG. - 20

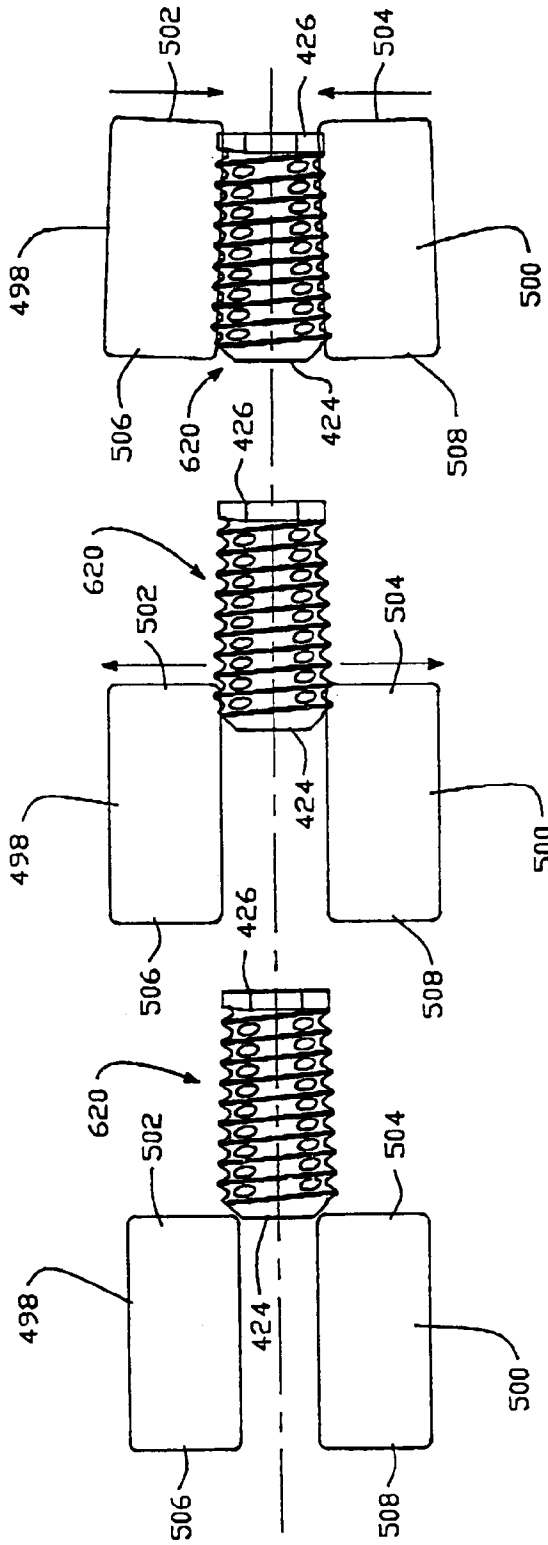


FIG.-23

FIG.-22

FIG.-21

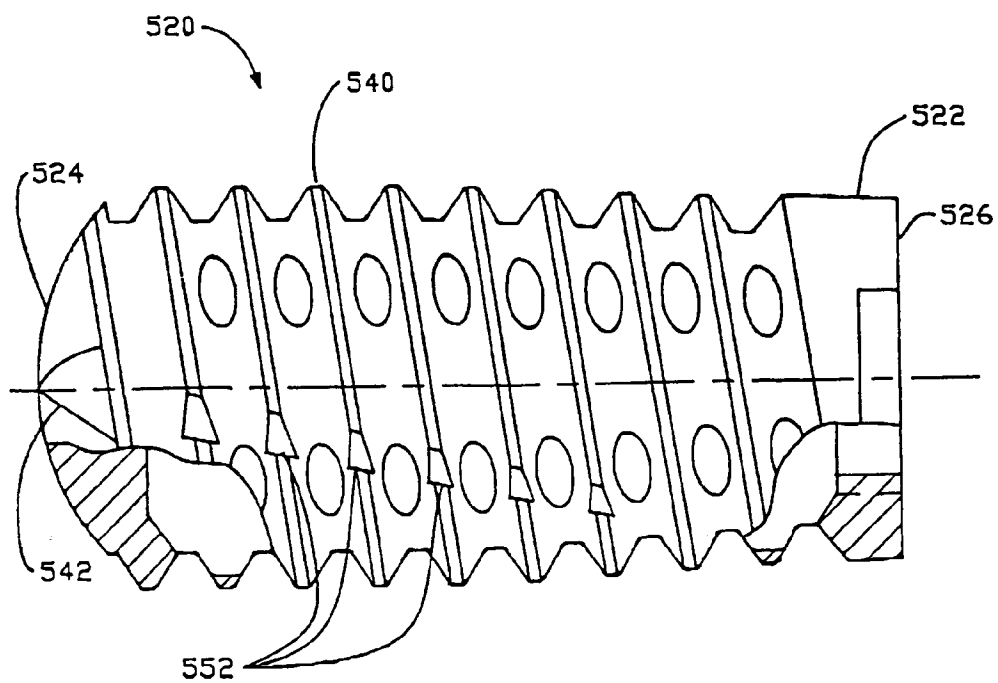


FIG. -24

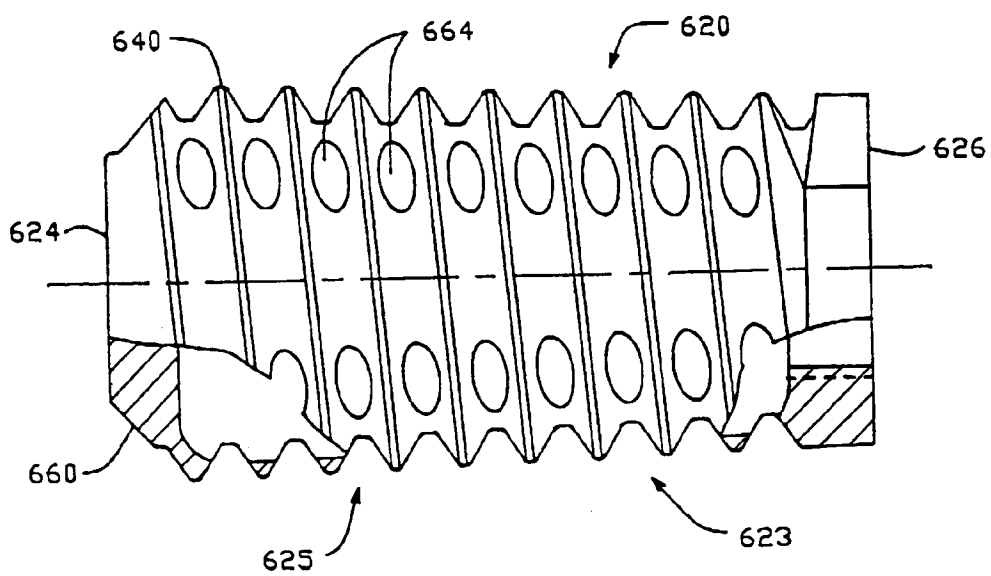


FIG. -25

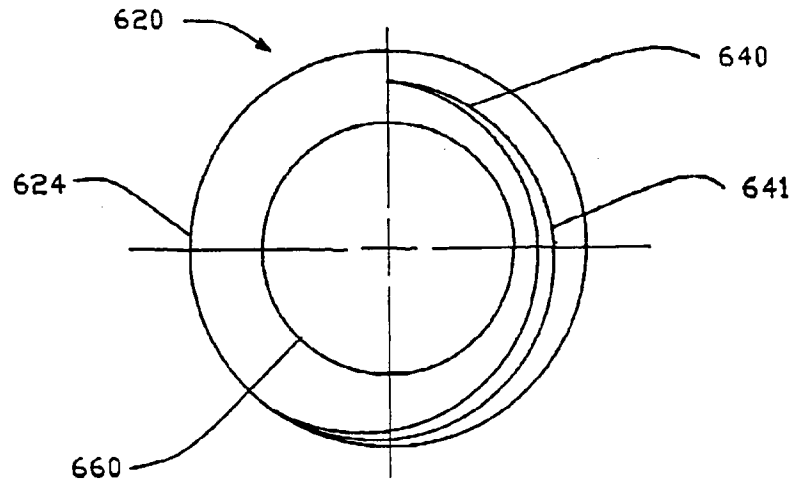


FIG.-26

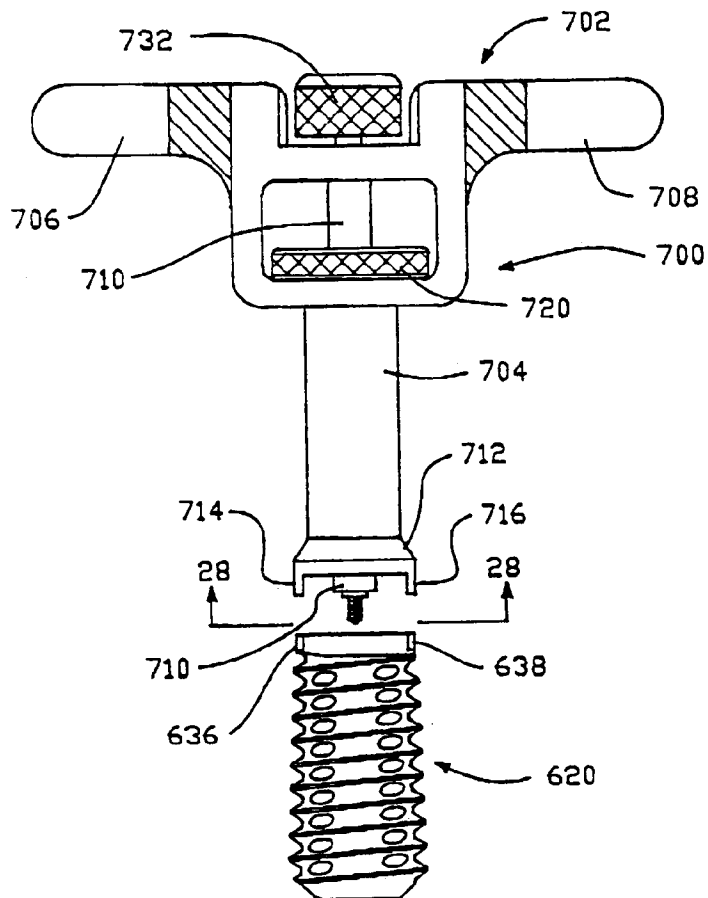


FIG.-27

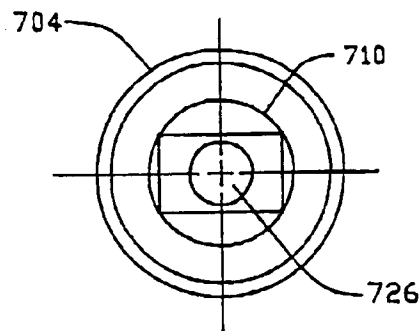


FIG.-28

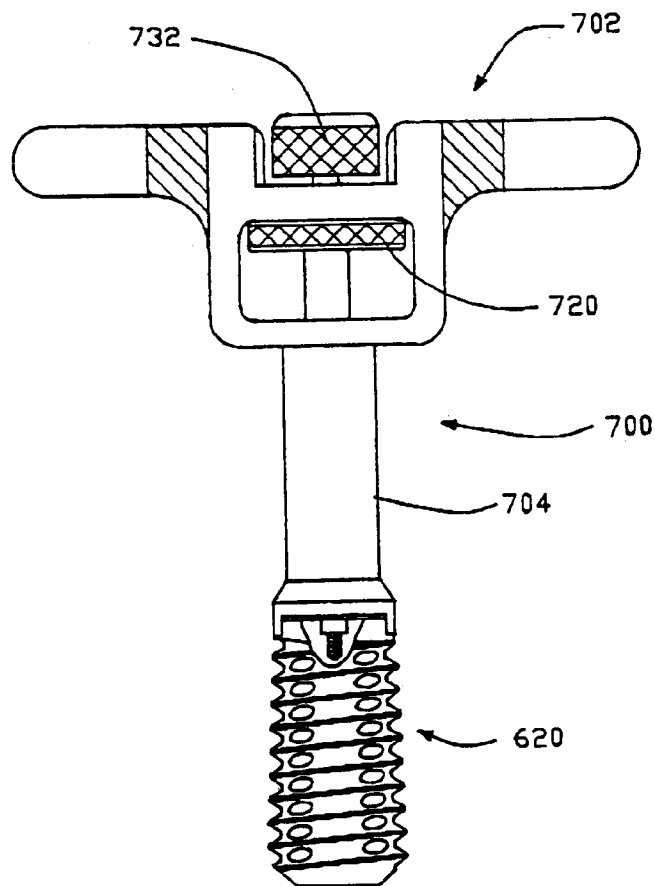


FIG.-29

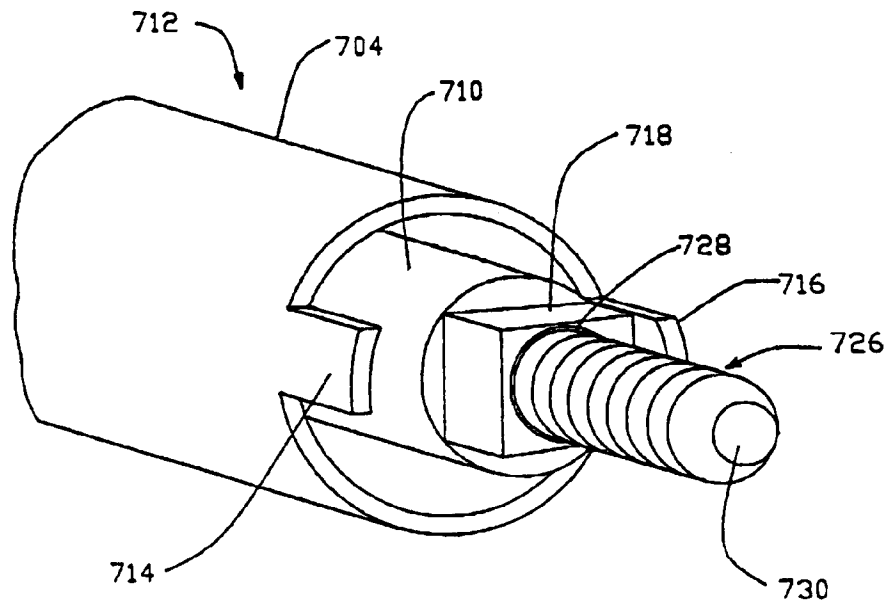


FIG. -30

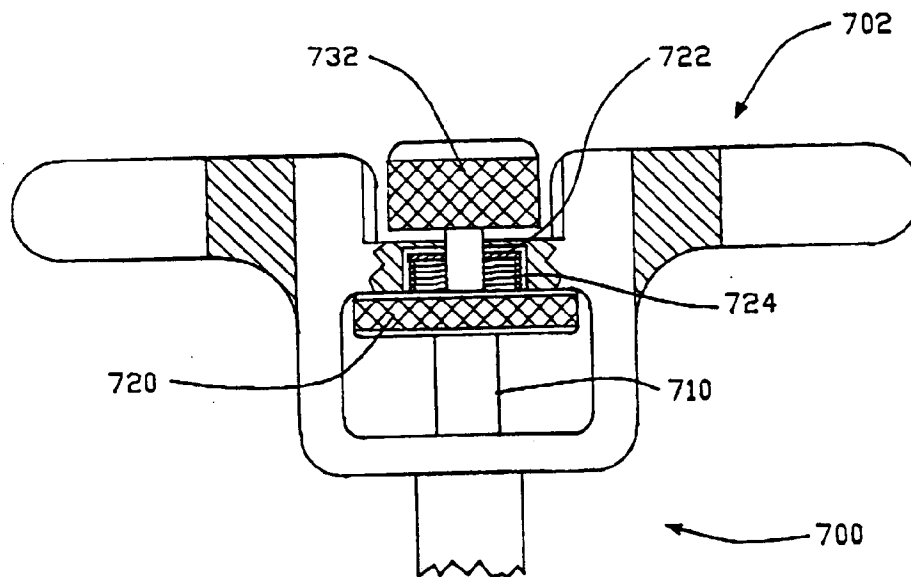


FIG. -31

(19)



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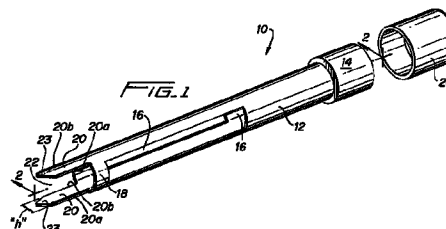
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(54) Method and instrumentation for surgical implant insertion

(57) A surgical retractor including a sleeve member having two opposed retractor arms (20) at its distal end portion. By inserting the retractor arms of the retractor within a space defined between adjacent bony structures, first and second supporting surfaces (20a, 20b) of each retractor arm respectively engage the opposed structures thereby distracting the structures, for performing a surgical procedure. A method for inserting a spinal implant is also disclosed. Instrumentation for performing the procedure is also disclosed.



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Description

BACKGROUND

1. Technical Field

The present disclosure generally relates to a method and associated instrumentation for implant insertion and, in particular, to a method and instrumentation for insertion of spinal implants to facilitate fusion of adjacent vertebral bodies.

2. Background of the Related Art

A large number of orthopedic procedures involve the insertion of either natural or prosthetic implants into bone or associated tissues. These procedures include, for example, ligament repair, joint repair or replacement, non-union fractures, facial reconstruction, spinal stabilization and spinal fusion. In a typical procedure, an insert, dowel or screw is inserted into a prepared bore formed in the bone or tissues to facilitate repair and healing. See, for example, U.S. Patent Nos.: 5,470,334 to Ross et al.; 5,454,811 to Huebner; 5,480,403 to Lee et al.; 5,40_,805 to Warren; 5,358,511 to Gattorna et al.; and 4,877,020 to Vich.

Some implants are particularly configured with cavities and bores to facilitate bony in growth and enhance anchoring of the implant at the insertion site. See, for example, U.S. Patent Nos.: 4,328,593 to Sutter et al.; 4,936,851 to Fox et al.; and 4,878,915 to Brantigan. Implants in the form of fusion cages having internal cavities to receive bone growth stimulation materials such as bone chips and fragments are disclosed, for example, in U.S. Patent Nos.: 4,501,269 to Bagby; 4,961,740 to Ray et al.; 5,015,247 to Michaelson; and 5,489,307 to Kuslich et al. These types of implants are particularly well suited for intervertebral spinal fusion procedures necessitated by injury, disease or some degenerative disorder of the spinal disc. Subsequently, there may be progressive degeneration leading to mechanical instability between adjacent vertebrae necessitating direct fusion of the vertebrae while maintaining a pre-defined intervertebral space. This fusion may be accomplished by the insertion of one or more of the specialized implants as discussed above and also discussed in commonly assigned U.S. Patent No. 5,026,373, the contents of which are incorporated herein by reference.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar spine. Fusions in the cervical area of the spine are primarily performed using a posterior approach. Typically, an implant such as a plug, dowel, prosthesis or cage is inserted into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these procedures to promote a "bone to bone" bridge, connective tissue and at least a portion of the distal tissue is removed. Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into

the softer, more vascularized cancellous region to facilitate bone growth across the implant.

One of the more critical tasks performed in the insertion of a surgical fusion implant, particularly, in intervertebral spinal fusion, is the formation of the implant receiving cavity or bore between/within the adjacent vertebrae. More particularly, the drilled bore must be equally centered within the intervertebral space and preferably parallel to the vertebral end plates to ensure removal of equal portions of bone from the adjacent vertebrae throughout the length of the cut and subsequent appropriate seating of the implant relative to the vertebral bodies.

Surgical instruments for spinal fusion implant insertion are known. For example, U.S. Patent No. 5,484,437 to Michelson discloses a method and apparatus incorporating an outer and an inner sleeve arrangement. The outer sleeve is positioned over the spinal distractor and has teeth at one end which are driven directly into the posterior surface of the adjacent vertebrae. The inner sleeve is positioned within the outer sleeve and serves to guide instruments such as a drill used to form the implant receiving bore. U.S. Patent Nos.: 5,487,307 to Kuslich et al.; 5,015,247 to Michelson; and 4,878,915 to Brantigan also disclose outer sleeves with teeth mounted to the vertebrae. Other arrangements include the use of guide rods which are placed in pilot holes formed in the vertebral bodies. The guide rods guide a bore forming hollow drill into the intervertebral space.

Although some current instrumentation and methods associated therewith for enhancing the placement of spinal fusion implants have been generally effective for their intended purposes, there exists certain limitations with the design of this instrumentation which detract from their usefulness. For example, the arrangement disclosed in the Michelson '437 patent and similar arrangements do not provide for automatic alignment of the outer sleeve to ensure that the bore formed by a drill introduced into the outer sleeve is in optimal alignment for a tapping procedure (if required) and reception of the spinal implant. Rather, such orientation is dependent directly upon the skill of the surgeon. Moreover, the outer sleeve, which is mounted via teeth only at its extreme distal end to the posterior surface of the adjacent vertebrae, is subject to disorientation or dislodgment during insertion and/or removal of the drill and/or tapping instrument. The use of guide rods increases the number of steps required to implant the fusion cage.

Accordingly, the present disclosure is directed to a method and associated instrumentation to facilitate the introduction of a fusion implant, which ensures optimal alignment of the drilled bore for reception of the fusion implant and, if appropriate, for bore tapping procedures. The instrumentation of the present disclosure also reduces the number of steps required for implantation of the fusion cage.

SUMMARY

Generally, the present disclosure is related to a method for performing a surgical procedure. The method includes the steps of providing a surgical retractor having proximal and distal end portions and having an opening therethrough to receive instrumentation, the distal end portion configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae. The method further includes the steps of at least partially inserting the retractor into the intervertebral space to distract adjacent vertebral and performing the surgical procedure with instrumentation inserted through the retractor. The surgical procedure particularly contemplated includes introducing a fusion implant through the surgical retractor and within the space defined between the distracted vertebrae.

The present disclosure is also directed to a method for effecting fusion of adjacent vertebral bodies, including the steps of accessing the intervertebral disc space, providing a retractor including a retractor sleeve having proximal and distal end portions with the distal end portion having opposed retractor arms extending in a general longitudinal direction, positioning the retractor arms within the intervertebral disc space whereby first and second supporting surfaces of each arm contact and distract opposed vertebral bodies, introducing a drill instrument into the sleeve and advancing the drill instrument within the sleeve to the intervertebral disc space, forming with the drill instrument a bore that penetrates at least partially into each opposed vertebral body, removing the drill instrument from the sleeve and introducing a fusion implant into the bore. The preferred method may further include the steps of introducing a tap instrument into the sleeve and advancing the tap instrument within the sleeve to the disc space, tapping with the tap instrument a thread within the bore such that the thread communicates into the opposing vertebral bodies, removing the tap from the retractor sleeve, introducing a fusion implant having a cage body with an external thread into the bore and screwing the cage body into the threaded bore.

The preferred fusion implant has a plurality of openings extending through the cage body whereby bone-growth inducing substances may be introduced into the cage body of the fusion implant to fuse with the adjacent vertebral bodies.

The present disclosure is also directed to instrumentation utilized to perform the spinal fusion implant surgery. In particular, a surgical retractor is provided including an elongated member having proximal and distal end portions and defining a longitudinal passageway for reception of surgical instrumentation. The distal end portion of the member includes first and second retractor arms extending in a general longitudinal direction. Each retractor arm has first and second supporting surfaces for engaging opposed adjacent tissue portions, e.g. opposed vertebral bodies. Each retractor arm defines a dimension between the first and second sup-

porting surfaces sufficient to distract the opposed tissue portions, e.g. vertebral bodies, upon insertion thereof. The retractor arms may each possess distal tapered portions for facilitating insertion into the intervertebral space. The first and second supporting surfaces of each retractor arm are preferably in general parallel relation to each other and the longitudinal axis of the sleeve member and in a preferred embodiment are substantially planar.

The present disclosure is also directed to a surgical tapping instrument for tapping an internal thread within a bore defined in adjacent vertebral bodies. The tapping instrument includes an elongated frame defining a longitudinal axis and having a distal tapping head. The tapping head includes a tapping thread for tapping a thread within the bony tissue and at least one conveyance channel having a directional component transverse to the longitudinal axis and dimensioned to collect bone material removed during the tapping procedure.

Other instrumentation to facilitate spinal implant insertion is also disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the disclosure are described hereinbelow with reference to the drawings wherein:

FIG. 1 illustrates a surgical retractor constructed in accordance with the principles of the present disclosure and utilized in distracting adjacent bony structures;

FIG. 2 is a cross-sectional view of the retractor taken along the lines 2-2 of FIG. 1;

FIG. 3A is a perspective view of a drilling instrument utilized in drilling a bore within the adjacent bony structures;

FIG. 3B is a cross-sectional view of the drilling instrument taken along the lines 3B-3B of FIG. 3A;

FIG. 4A is an axial plan view of the drilling head of the drilling instrument;

FIG. 4B is a side plan view of the distal end portion of the drilling head illustrating the end and side cutting surfaces of the drilling head;

FIG. 5 is a perspective view of a tapping instrument utilized in tapping an internal thread in the bore formed by the drilling instrument;

FIG. 6 is an axial plan view of the tapping head of the tapping instrument of FIG. 5;

FIG. 7A is a perspective view of an insertion instrument and a detached T-handle utilized in inserting an implant within the tapped bore formed by the tapping instrument;

FIG. 7B is an enlarged cross-sectional view illustrating a mounting arrangement for mounting the T-handle to the insertion instrument with the mounting mechanism in a disengaged position;

FIG. 7C is a view similar to the view of FIG. 7B illustrating the mounting mechanism in an engaged

position;

FIG. 8 is a perspective view of the implant to be inserted into the tapped bore formed between the adjacent bony structures;

FIG. 9 is a perspective view of the implant of FIG. 8 illustrating the body and detached end cap;

FIG. 10A is a perspective view illustrating mounting the distal end of insertion instrument of FIG. 7A to the implant of FIG. 8;

FIG. 10B is a cross-sectional view illustrating engagement of the spring-loaded ball detent of the insertion instrument with the interior surface of the implant;

FIG. 11 is a side plan view illustrating positioning of the retractor of FIG. 1 within an intervertebral space between adjacent vertebrae in accordance with a preferred method for inserting the implant;

FIG. 12 is a side plan view illustrating insertion of the drilling instrument of FIG. 3 into the retractor to drill a bore within the adjacent vertebrae;

FIG. 13 is a side plan view illustrating insertion of the tapping instrument of FIG. 5 into the retractor to tap an internal thread in the bore;

FIG. 14 is a side plan view illustrating insertion of the insertion instrument with mounted implant through the retractor and placement of the implant within the tapped bore;

FIG. 15 is a side plan view of a syringe containing bone inducing substances;

FIG. 16 is a side plan view illustrating loading of the bone-inducing substances into the implant with the use of forceps;

FIG. 17 is a side plan view of a cap mounting instrument utilized in mounting the implant end cap onto the body of the implant;

FIG. 18 is an axial plan view of the mounting head of the mounting instrument of FIG. 17;

FIG. 19 is a perspective view of the mounting head and the end cap;

FIG. 20 is a view illustrating insertion of the mounting instrument and end cap within the surgical site to mount the end cap to the body of the implant; and FIG. 21 is an enlarged top view in partial cross-section of a pair of implants positioned into the intervertebral space of a lumbar spinal section.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

The preferred embodiments of the method and instrumentation disclosed herein are discussed in terms of orthopedic spinal fusion procedures and instrumentation. It is also envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present method and instrumentation finds application in both open and minimally invasive procedures including

endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

The following discussion includes a description of each instrument utilized in performing a spinal fusion followed by a description of the preferred method for spinal fusion utilizing the instrumentation in accordance with the present disclosure.

In the discussion which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closer to the operator, while the term "distal" will refer to the portion which is further from the operator.

Referring now to the drawings in which like reference numerals identify similar or identical elements throughout the several views, FIG. 1 illustrates in perspective view a surgical retractor of the present disclosure. Retractor 10 is particularly contemplated for distracting adjacent bony structures, e.g., adjacent opposed vertebral bodies, to facilitate the insertion and application of an implant, for providing a cannula for insertion of the instruments, and for ensuring proper alignment of the instrumentation and accurate insertion of the implant. Although described for spinal procedures, it is envisioned that retractor 10 may also be utilized to distract other structures as well including joints, ligaments, etc..

Referring now to FIGS. 1-2, retractor 10 includes sleeve 12 defining longitudinal axis "a" and having enlarged head 14 disposed at a proximal end thereof. Sleeve 12 defines a longitudinal opening extending therethrough to receive surgical instrumentation described below. Sleeve 12 and enlarged head 14 are preferably monolithically formed of a suitable rigid material including stainless steel, aluminum alloy or the like. Sleeve 12 may be formed of a suitable polymeric material as well. Sleeve 12 may be a variety of sizes including, for example, 12 mm, 14 mm, 16 mm and 18mm in diameter. The retractor size utilized will generally correspond to the diameter of the instrumentation and/or implant to be applied.

Sleeve 12 may include first and second longitudinally extending openings 16 formed in its outer wall. Openings 16 are diametrically arranged with relation to each other and terminate at their distal ends in collar 18. Each opening 16 extends radially for about between 10%-50% the circumference or perimeter of sleeve 12 and longitudinally for greater than 50% the length of sleeve 12. Openings 16 are contemplated to permit the lateral introduction of surgical instrumentation required to carry out the fusion procedure as an alternative to introducing the instrumentation through the open proximal end of sleeve 12. These openings 16 also enhance illumination at the surgical site.

Sleeve 12 further includes first and second diametrically opposed retractor arms or tangs 20. Retractor arms 20 extend distally from collar 18 in a general longitudinal direction parallel to one another and define longitudinal slotted portion 22. Each arm 20 has an arcuate

outer surface (i.e., defining a radius of curvature substantially equivalent to the radius of curvature of the remaining portion of the sleeve). Each retractor arm 20 has first and second vertebrae supporting surfaces 20a, 20b in general parallel relation to each other and preferably parallel to the longitudinal axis of sleeve 12. In the illustrated embodiment, supporting surfaces 20a, 20b are substantially planar. The height "h" of each arm 20 (i.e., the distance between supporting surfaces 20a, 20b) corresponds to the height of the intended distraction distance between adjacent tissue portions, i.e. adjacent vertebrae. For example, in spinal fusion application, the height "h" of each arm 20 ranges from about .3 to .4 inches and more preferably from about 0.28 to about 0.35 inches. One skilled in the art will readily appreciate that this dimension can be varied as needed depending upon the procedure. Each arm 20 further includes tapered end portions 23 defining a generally V-shaped configuration. End portions 24 facilitate insertion of retractor arms 20 within the surgical site, e.g., within the intervertebral space.

Referring still to FIGS. 1-2, an impact end cap 26 is positionable over enlarged head 14 and preferably has an inner diameter approximating the outer diameter of the head 14 to form a releasable frictional fit between the two components. Impact cap 26 is intended to receive the impact of a driving instrument used to insert retractor 10 within the bony tissue as will be discussed. Such impaction, drives the arms 20 of sleeve 12 into the disc space (with the height h spanning the space) and distracts the opposing vertebrae bodies as surfaces 20a engage the upper (or lower) vertebral body and surface 20b engages the opposing vertebral body, thereby firmly mounting the retractor 20 to maintain its alignment and orientation and ensure that an equal amount of material is cut on both vertebral end plates when a drill is inserted therethrough (described below).

Referring now to FIGS. 3A-3B, the drilling instrument used to form a bore between/within the adjacent vertebrae will be described. Drilling instrument 40 includes drill shaft 42 and extension shaft 44 which is connectable to the drill shaft 42. Drill shaft 42 has an internally threaded bore 46 at its proximal end and drill bit 48 mounted at its distal end. Extension shaft 44 has a proximal mounting section 50 which cooperatively engages corresponding structure of a T-handle (the distal portion of the T-handle is depicted in FIG. 3A) to mount the handle to the extension shaft 44. The particular mounting arrangement utilized to effect the mounting of the T-handle to extension shaft 44 will be discussed in greater detail hereinbelow with later reference to Figs. 7A-7C. Extension shaft 44 further includes collar 52 and distal threaded portion 54 extending from the collar 52. Collar 52 includes an internal thread which cooperates with threaded portion 54 to mount the collar 52 to extension shaft 44. Collar 52 is preferably fixedly mounted to threaded portion 54 by welding or the like. Distal threaded portion 52 cooperatively engages internal threaded bore 46 of drill shaft 42 to connect the two

components.

Extension shaft 44 has first and second collars 56, 58 which are threaded on threaded portion 54. Each collar 56, 58 is moveable on threaded portion 54 between a position adjacent stationary collar 52 and a position adjacent drill shaft 42. First collar 56 serves as a positioning collar, i.e., by adjusting the positioning of first collar 56 on threaded portion 54, the depth of penetration of drill shaft 42 into the bony structures may be adjusted. Second collar 58 serves as a locking collar to selectively lock the first collar 56 at the predetermined location on threaded portion 54. In particular, when drilling instrument 40 is inserted within sleeve 12 of the retractor of FIG. 1, positioning collar 56 engages the proximal end face of enlarged head 14, thus, precluding further distal advancement of drilling instrument 40 within the bony structures. Thus, by selectively adjusting the location of positioning collar 56 on threaded portion 54 and locking the collar 56 with locking collar 58 at the desired position, the length (depth) of the bore formed in the bony structures (e.g., vertebrae) is readily controllable. Thus, the depth of the hole is predetermined to accommodate the length of the fusion cage to be implanted. Extension shaft 44 also includes depth markings 60 on its outer surface. Depth markings 60 are calibrated to indicate to the surgeon the degree of penetration of drill shaft 42, thus, further assisting the surgeon in monitoring the length of the bore formed by drilling instrument 40.

Referring now to FIGS. 4A-4B, drill bit 48 includes a twin cutting surface design incorporating end cutting edges 62 located on flutes 64 and side cutting edges 66. These edges 62, 66 cooperate to shear or cut the tissue rather than tear or pull the soft tissue as in conventional bone drills. The end cutting edge 62 cleanly cuts the soft disc material as the side cutting edges 66 cut the end plates substantially simultaneously. Thus, the bore formed by drill bit 48 is clean and exceptionally precise and less manual pressure on the drill is required to form the hole. As depicted in FIG. 4B, which is an enlarged view of the distal end portion of drill bit 48, the drill bit 48 defines the following parameters. Angle "a" is the degree of forward projection of the outer peripheral surface of the distal end of the drill bit 48 relative to a plane "t" transverse to the longitudinal axis "l" defined by the radial center of the drill bit 48. Angle "a" ranges from about 0° to about 10° and is preferably about 2°. Angle "B" is the degree of the angle of attack for end cutting edges 62 relative to the transverse plane "t" and ranges from about 2° to about 15°, and is preferably about 5°. Angle "O" is the degree of twist defined by side cutting edges 62 relative to the transverse plane "t" and ranges from about 15° to about 60°, and is preferably about 45°.

Referring now to FIGS. 5-6, tapping instrument for forming an internal thread within the drilled bore will be discussed. Tapping instrument 70 includes proximal mounting portion 72 which cooperatively engages T handle (discussed below) and distal tapping thread por-

tion 74. Distal tapping thread portion 74 includes threaded cutting edges 76 and at least one spiral conveyance channel [3 are shown] extending longitudinally from the distal end of tapping thread portion 74 to the proximal end of the thread portion 74. The conveyance channels having a directional component transverse to the longitudinal axis and preferably in the form of a helical groove. Conveyance channel 78 is dimensioned to receive bone material deburred by the cutting edges 76 during the tapping procedure and to continually transmit the bone material proximally through the channel 78 to avoid undesired material build-up at the tapping site. In this manner, tapping instrument 70 may be used to completely tap the internal thread within the bore without interruption of the tapping procedure.

Tapping instrument 70 further includes annular rings 80 integrally formed at an intermediate portion of the instrument. Annular rings 80 facilitate grasping engagement of tapping instrument 70 by the user. Several depth markings 82 are provided on the external surface of the tapping instrument 70. Depth markings 82 indicate the depth of insertion of tapping instrument 70 within the retractor 10 of FIG. 1 and the bore defined in the adjacent bony structures. Bevel 75 facilitates insertion of the tapping instrument 70 into the retractor 10.

Referring now to FIGS. 7A-7C, the insertion instrument for inserting the fusion implant into the tapped bore and the T-handle will be discussed. Insertion instrument 100 includes elongated member 102 having handle mounting section 104 at its proximal end and rounded head 108 at its distal end. Although the elongated member 102 is shown having sections of different diameters, in an alternate embodiment, the elongated member 102 is of substantially uniform diameter between its proximal and distal end portions. Handle mounting section 104 is configured to engage T-handle 110 to mount the T-handle to the insertion instrument. In a preferred mounting arrangement, T-handle 110 includes handle body 112, a first sleeve 114 mounted to the body 112 and a second sleeve 116 mounted with respect to the first sleeve 114. First sleeve 114 has an inner surface correspondingly dimensioned to engage hexagonal portion 118 of handle mounting section 104. An internal spring loaded ball system 120 is defined adjacent second sleeve 116 and is configured to engage an annular groove 122 defined in handle mounting section 104. Second sleeve 116 is mounted for relative movement between an unlocked position (FIG. 7B) and a locked position (FIG. 7C). In the locked position, ball system 120 is forced radially inwardly into annular groove 122. Spring 124 normally biases second sleeve 116 to the locked position. As depicted in FIG. 7B, in the unlocked position, second sleeve 116 is retracted to release ball system from annular groove 122.

Handle mounting section 104 of insertion instrument 100 is identical to the mounting sections 50, 72 of drilling instrument 40 and tapping instrument 40, 70, respectively. Thus, T-handle 110 may be mounted and used with drilling instrument 40 and tapping instrument

70 in an identical manner.

Referring now to FIGS. 8-9, one type of implant designed for use in spinal fusion procedures and with which the instrumentation of the present disclosure can be used is illustrated. This implant is generally disclosed in U.S. Patent No. 5,026,373 to Ray, the contents of which are incorporated herein by reference, and is commonly referred to as a "fusion cage".

Implant or fusion cage 200 includes body portion 202 having an internal cavity or hole 204 for accommodating bone-growth inducing substances. One end 206 of cage body 202 is closed and defines a rounded or bull-nosed configuration to facilitate insertion of the fusion cage relative to one or more bony structures. The other end 208 defines an opening which communicates with internal cavity 204. The outer surface of the cage body 202 includes a single continuous thread 208 (preferably V-shaped) having a plurality of raised turns with valleys defined between adjacent turns.

A plurality of perforations 210 are disposed within the threads and extend through the outer surface of the cage body 202 to provide direct communication between the outer surface and the inner cavity 204. The perforations 210 permit immediate contact between the bone growth inducing substances within the inner cavity 204 and the bone structure when the cage body 202 is mated to the bone structure, e.g., adjacent vertebrae. An end cap 212 is mountable to the open end of cage body 202 to enclose the bone-growth inducing substances within the interior cavity. End cap 212 is preferably fabricated from a flexible polymeric material such as polyethylene and is dimensioned to snap into a groove or recess 214 defined in the interior end of cage body 202. End cap 212 includes an axial opening 216 and four equidistally spaced peripheral notches 218.

Referring now to FIGS. 10A-10B, to mount the insertion instrument 100 of FIG. 7A to fusion cage 200, the rounded head 108 of the instrument 100 is positioned within the interior cavity 204 of cage body 202 with diametrically opposed slots 109 (only one is shown) engaging the longitudinal ribs 203 formed within the cage body 202. Once mounted, the cage body 202 is rotated by rotation of the instrument 110. Head 108 may be inserted within interior cavity 204 to a position almost adjacent closed end 206. A spring loaded ball detent system 126 associated with the rounded head 108 frictionally retains the head 108 within cage body 202 as depicted in FIG. 10B. A pair of opposed alignment bars 119 (only one is shown) formed on elongated shaft 102 (Fig. 7A) are positioned in substantial alignment with slots 109 to indicate to the user the orientation of the fusion cage 200.

Application of Instrumentation

The use of the instrumentation kit in conjunction with the insertion of the fusion cage 200 of FIG. 8 into an intervertebral space defined between adjacent lumbar vertebrae will be described. The subsequent

description will be particularly focused on an open posterior spinal fusion procedure, however, it is to be appreciated that an anterior approach is contemplated as well.

The intervertebral space is accessed utilizing appropriate retractors, e.g., laminar retractors, dural extractors to expose the posterior vertebral surface. Thereafter, retractor 10 of FIG. 1 with impactor cap 26 mounted thereon is positioned adjacent the intervertebral space. With reference to FIG. 11, retractor arms 20 are inserted within the intervertebral space and the retractor 10 is gently impacted into the space with a mallet. The preferred orientation of retractor arms 20 within the intervertebral space is shown in FIG. 11. As shown, retractor arms 20 are arranged such that first and second supporting surfaces 20a, 20b of each retractor arm respectively engages the opposed vertebral bodies V_1 , V_2 . Upon insertion of retractor arms 20, the vertebral bodies V_1 , V_2 are distracted whereby the retractor arms 20 become firmly lodged within the intervertebral space. The arrangement of retractor arms 20 provides a double point contact with each vertebral body (curved end plate), i.e., the first supporting surfaces 20a of retractor arms 20 engage vertebral body V_1 at two different locations and in spaced relation. The second supporting surface 20b engage vertebral body V_2 in the same manner. Thus, the load exerted by vertebral bodies V_1 , V_2 is distributed at two different locations on retractor 10 and along the entire lengths of the supporting surfaces 20a, 20b thereby firmly and uniformly loading the retractor 10 in the intervertebral space. It is also to be noted that as discussed above, the particular arrangement of the retractor arms 20 within the intervertebral space automatically appropriately aligns retractor 10 with relation to the vertebral bodies V_1 , V_2 , i.e., in parallel relation with the vertebral end plates for the subsequent drilling process. Tapered surfaces 24 of retractor arms 20 facilitate entry of the retractor arms 20 into the intervertebral space. The depth of penetration of retractor arms 20 is limited by collar 18 as described above.

Referring now to FIG. 12, the drilling instrument of FIG. 3A is now used to prepare the disc space and vertebral end plates for insertion of the fusion implant. The cutting depth of drilling instrument 40 is adjusted as desired (i.e., to correspond to the length of the fusion cage) by adjusting the positional collar 56 and securing the collar 56 at the desired position with locking collar 58 as described above. With the T-handle 110 mounted to drilling instrument 40 in the manner described above, the instrument is introduced into retractor 10 and advanced to contact the posterior surface of the vertebral bodies V_1 , V_2 . Drill bit 48 communicates with vertebral bodies V_1 , V_2 through slotted opening 22 defined between retractor arms 20 (FIG. 1). Drilling instrument 40 is advanced into the intervertebral space by rotating T-handle 110 in the direction indicated by the directional arrow of FIG. 12 until positional collar 56 engages the proximal end of enlarged head 18 of the retractor 10.

This shears the soft tissue and cuts the bone as described above. Depth markings 60 are also monitored to further assist the surgeon. Thereafter, drilling instrument 40 is removed by rotating T-handle 110 in the opposite direction and the instrument 40 is removed from the retractor 10.

When juxtaposed sides of the adjacent vertebral disc have been adequately prepared by drilling the holes and completely removing any remaining soft tissue, tapping instrument 70 of FIG. 5 is selected and attached to the T-handle 110. The purpose of the tapping instrument 70 is to cut the threads into the opposing vertebral endplates. This ensures that the implant will be positioned correctly and will have the correct purchase into the endplates for immediate bone graft material to endplate contact. With reference now to FIG. 13, tapping instrument 70 is inserted into retractor 10 and positioned adjacent the drilled bone. With retractor 10 as a direct guide, T-handle 110 is rotated in the direction of the directional arrow of FIG. 13 while simultaneously applying sufficient downward (distal) pressure on the T-handle 110 to advance the tapping instrument 70 and promote even purchase into the endplates. Upon advancement of the tapping instrument 70, the deburred bone chips collect within conveyance channel 78 of tapping head 74, and are conveyed proximally during rotational movement of the tapping head away from the tapping site. Tapping instrument 70 is advanced into the bone until the desired depth has been achieved, which occurs when the distal end of tapping head 74 "bottoms out" on the bone. To further ensure that the tapping instrument 70 reaches the proper depth, the depth markings 82 on tapping instrument 70 are also monitored. Tapping head 74 communicates with vertebral bodies V_1 , V_2 through slotted openings 22 defined between the retractor arms 20. When tapping instrument 70 reaches the appropriate depth, the tapping instrument 70 is rotated via T-handle 110 in an opposite direction to back the instrument out of the bone and the instrument 70 is removed from the retractor 10.

With reference now to FIG. 14, attention is focused on the insertion of the selected fusion implant 200. Cage body 202 is mounted onto insertion instrument in the manner described in connection with FIGS. 10A-10B. With T-handle 110 attached in the manner described above, insertion instrument 100 with mounted cage body 202 is inserted into retractor 10 and the cage body 202 is positioned within the tapped bore by rotating insertion instrument in the direction depicted in FIG. 14. Cage body 202 is advanced until it is completely seated with the bore. The indicator lines on insertion instrument 100 assist the surgeon in determining when the cage is in proper position. Alignment bars 119 indicate to the user the orientation of the cage to assist in ensuring that the perforations 210 are in communication with the vertebral end plates when the cage is finally positioned. Insertion instrument 100 is then removed from retractor 10.

With reference now to FIG. 15, bone growth induc-

ing substances are harvested from, e.g., the iliac crest, and can be packed into a syringe body or tube "s" (as shown in FIG. 15) or other holding device. As depicted in FIG. 16, with the use of forceps "f", the bone growth inducing substances are removed from the syringe "s" and introduced into the cage body 202 until the cage body 202 is completely filled with bone growth inducing substances. The bone growth inducing substances can be lightly impacted to pack the cage.

With reference to FIGS. 17-19, after filling cage body 202, the end cap 212 is mounted to the cage body 202. A preferred instrument 300 for applying end cap 212 includes handle 302 and elongated portion 304 connected to the handle and extending distally therefrom. At the distal end of elongated portion 304 is mounting head or section 306. Mounting head 306 includes distal annular portion 308 with annular nub 310 projecting therefrom and four equidistantly spaced flanges 312. Flanges 312 extend in a radial direction and are preferably spaced about 90° apart as best depicted in FIG. 17. Flanges 312 engage the end cap 312 to limit proximal flexure of the end cap 312 as it is mounted to the cage body 202. In the mounted condition of end cap 212 onto instrument 300, annular nub 310 of the instrument 300 is received within annular opening 216 of end cap 212. Preferably, annular nub 310 and opening 216 are correspondingly dimensioned such that a friction fit between the two components is established.

With reference now to FIG. 20, instrument 300 with mounted end cap 212 is introduced into the operative site and advanced to cage body 202. Thereafter, end cap 212 is mounted to cage body 202 by inserting the end cap 212 within the interior cavity whereby the end cap 212 snaps into correspondingly dimensioned groove 214 (FIG. 9) defined in the cage body 202. During insertion, the peripheral area of end cap 212 is permitted to deform due in part to the flexible characteristics of its material of fabrication and to notches 216, thus enabling the end cap 212 to pass within the cage body 202. It is to be noted that during insertion, flanges 312 of instrument 300 (FIG. 19) prevent any tendency of end cap 212 to rotate relative to the instrument. With end cap 212 mounted within cage body 202, instrument 300 is removed.

FIG. 21 illustrates two lateral fusion implants 200 inserted within the lumbar intervertebral space. The second fusion cage 200 is inserted in accordance with the method and instruments previously discussed.

While the above description contains many specifics, these specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof. For example, the forceps and/or end cap insertion tool can be inserted through the retractor 10 prior to removal of the retractor 10. Those skilled in the art will envision many other possible variations that are within the scope of the claims appended hereto. The claims identify embodiments of the invention additional to those

described in detail above.

Claims

1. A surgical retractor instrument comprising an elongated member having proximal and distal end portions and defining a longitudinal passageway for reception of surgical instrumentation, the distal end portion having first and second retractor arms extending in a general longitudinal direction, each retractor arm having first and second supporting surfaces for engaging opposed adjacent tissue portions, each retractor arm defining a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof
2. The surgical retractor according to claim 1 wherein the first and second supporting surfaces of each retractor arm are substantially planar.
3. The surgical retractor according to claim 1 or 2 wherein each retractor arm has a tapered end portion for facilitating insertion into the intervertebral space.
4. A surgical retractor for use in distracting adjacent vertebrae, the retractor comprising:
 - an elongate body having a proximal end and a distal end and defining a longitudinal passageway therebetween; and
 - first and second retractor arms extending longitudinally from the distal end of the elongate body, each retractor arm defining a first vertebra supporting surface and a second vertebra supporting surface, the first and second vertebra supporting surfaces of each retractor arm being spaced thereon at a predetermined distraction distance.
5. The surgical retractor according to claim 4 wherein the retractor arms each possess distal tapered portions for facilitating insertion into the intervertebral space.
6. The surgical retractor according to claim 4 or 5 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation.
7. The surgical retractor according to claim 6 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation to a longitudinal axis of the elongate body.
8. The surgical retractor according to any one of the preceding claims wherein the elongate body includes at least one longitudinal opening defined in an intermediate wall portion.

9. A surgical tapping instrument for tapping an internal thread within a bore defined in bony tissue, comprising an elongated frame defining a longitudinal axis and having a distal tapping head, the tapping head including a tapping thread for tapping a thread within the bony structure and at least one conveyance channel dimensioned to collect bone material removed during the tapping procedure, the one conveyance channel having a directional component transverse to the longitudinal axis.
10. The surgical tapping instrument according to claim 9 wherein the one conveyance channel is a helical groove.

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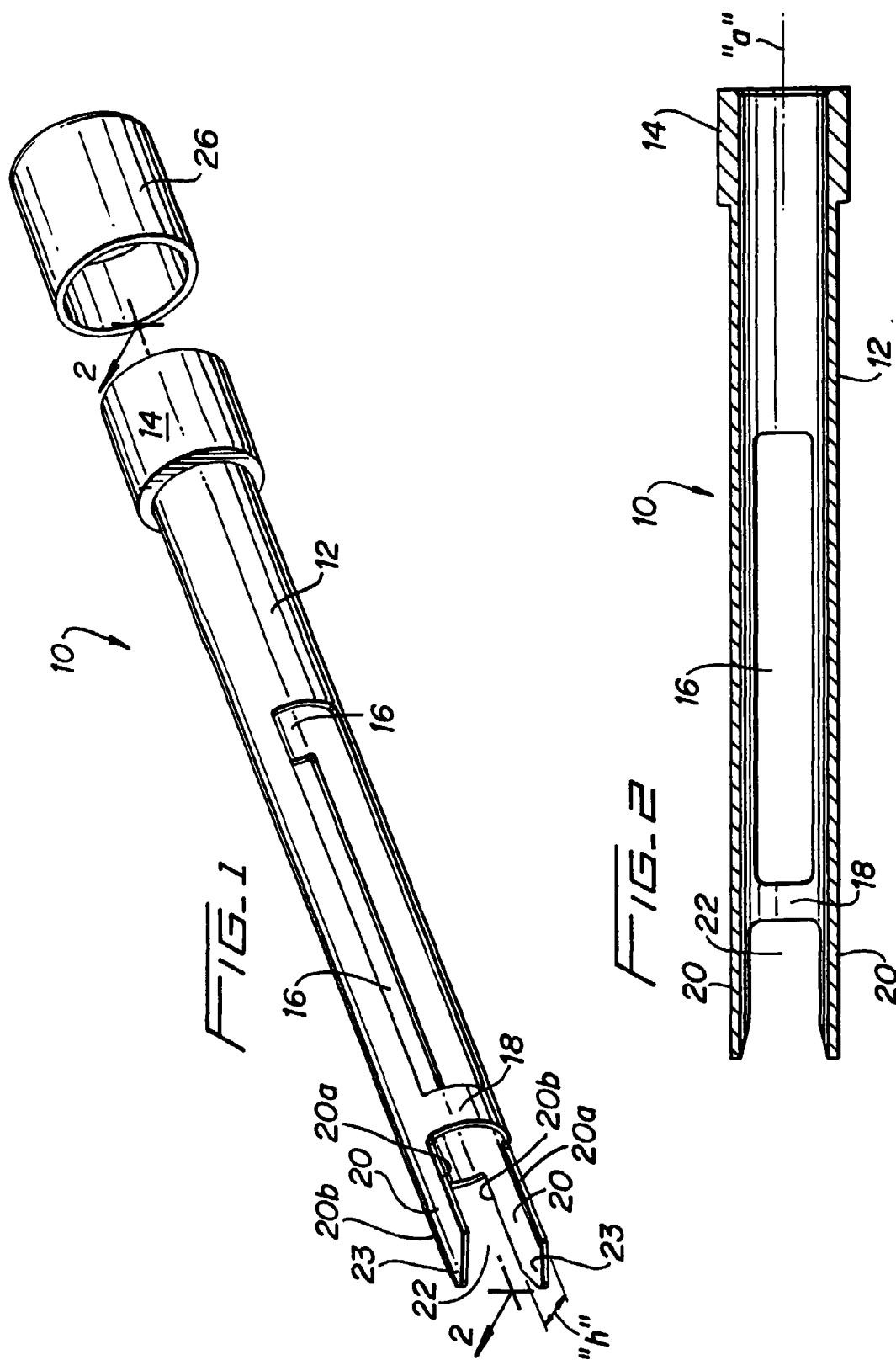
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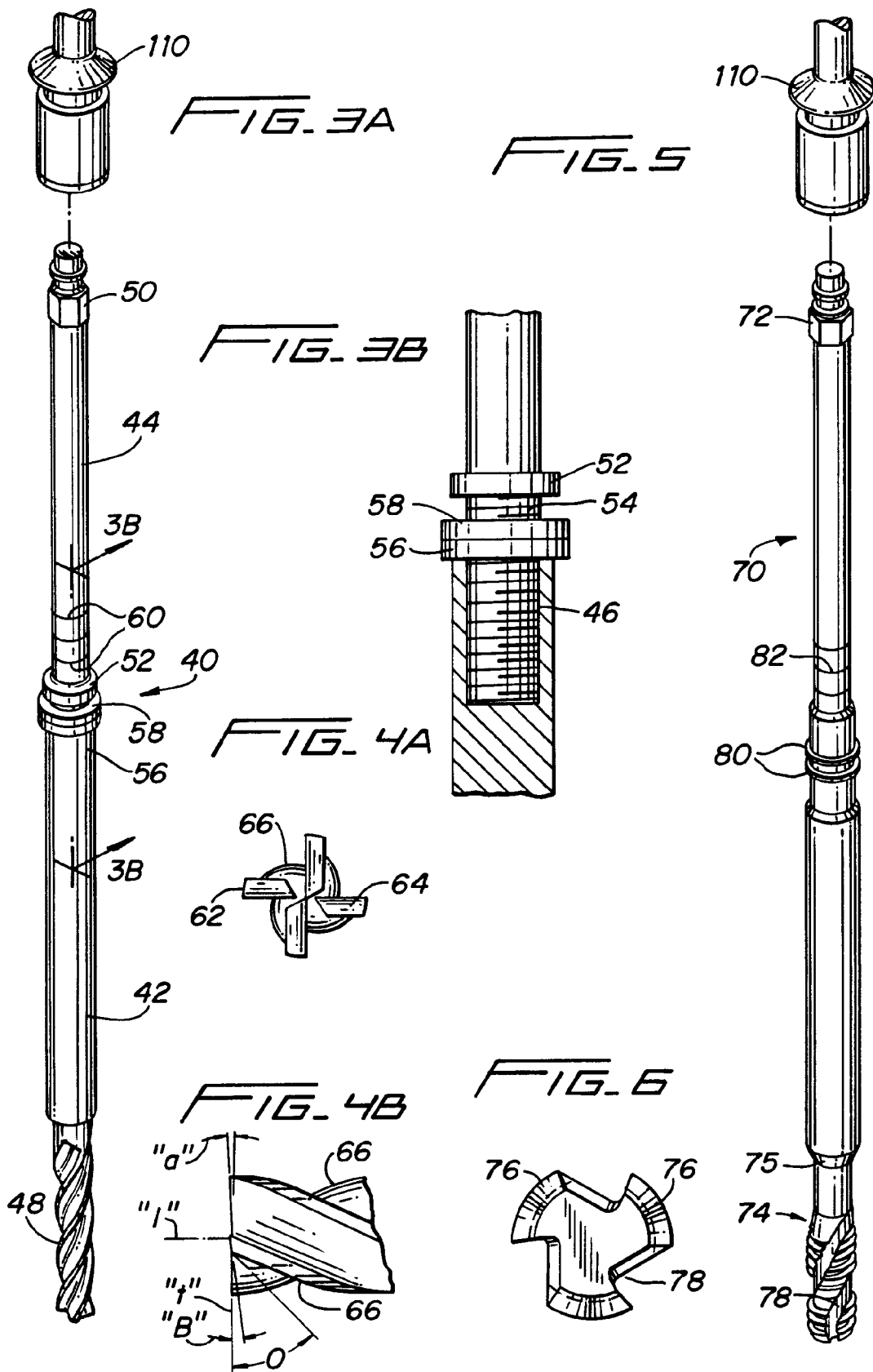
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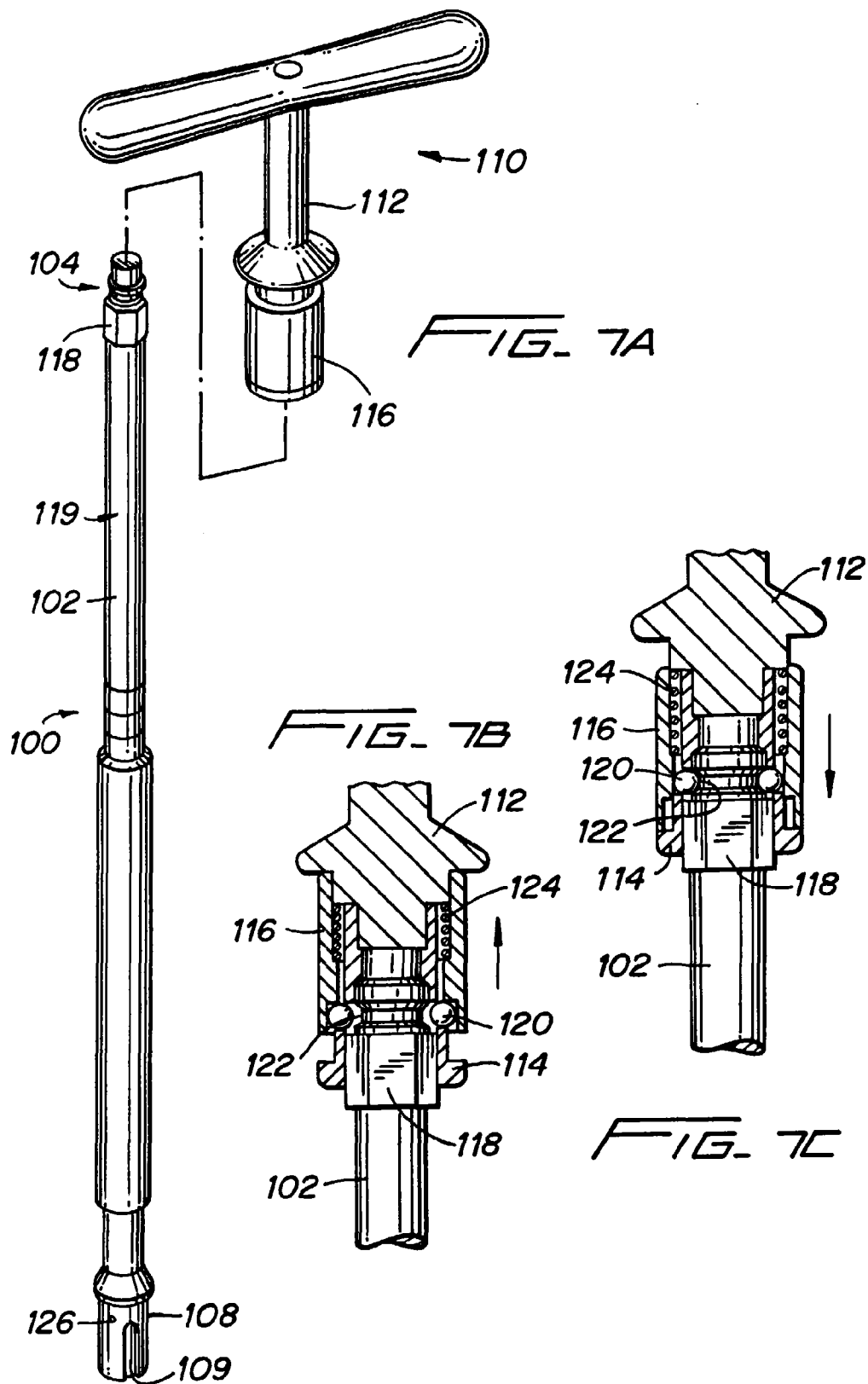
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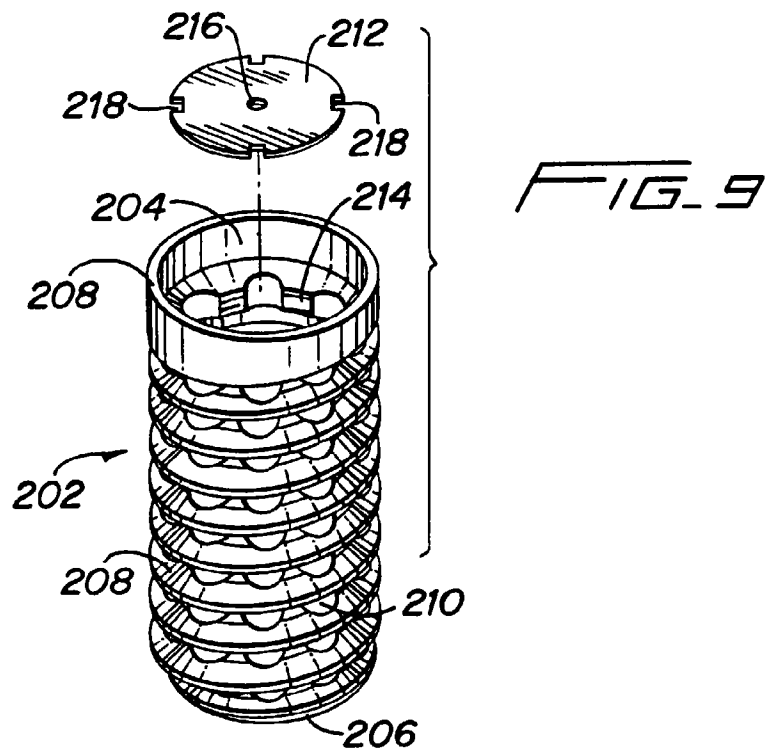
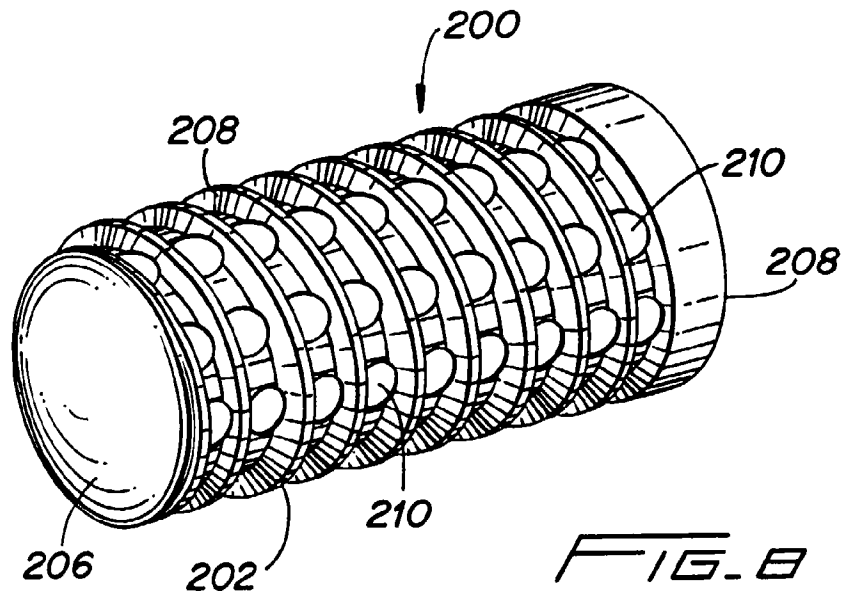
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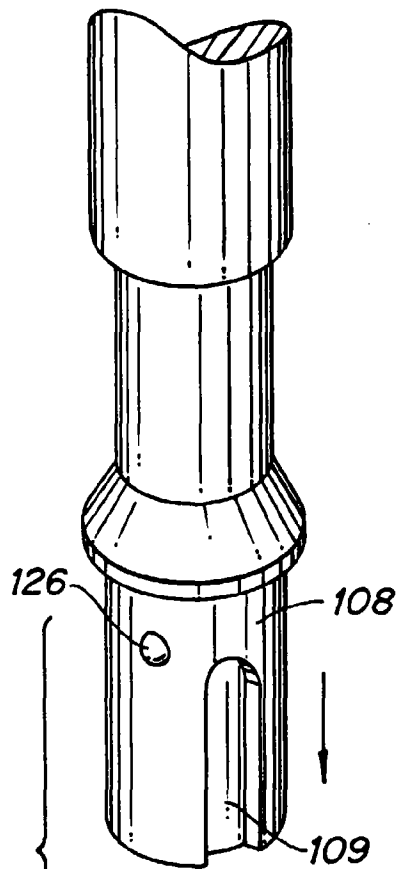


FIG. 10A

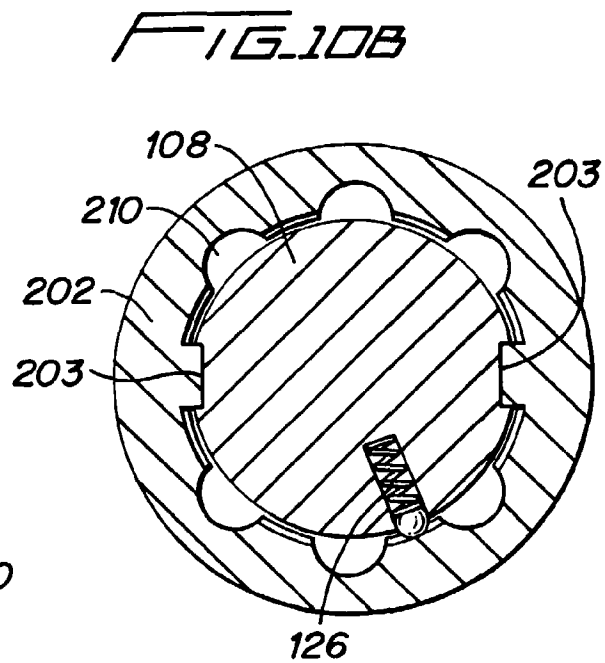
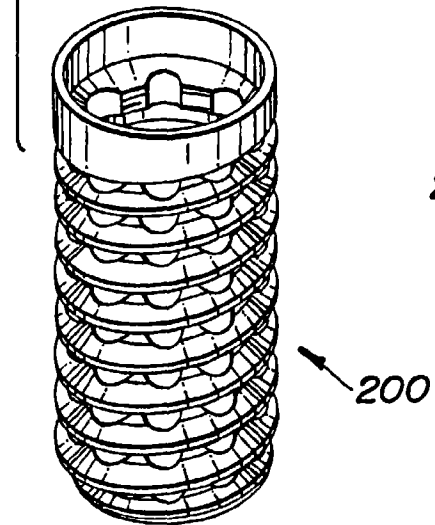
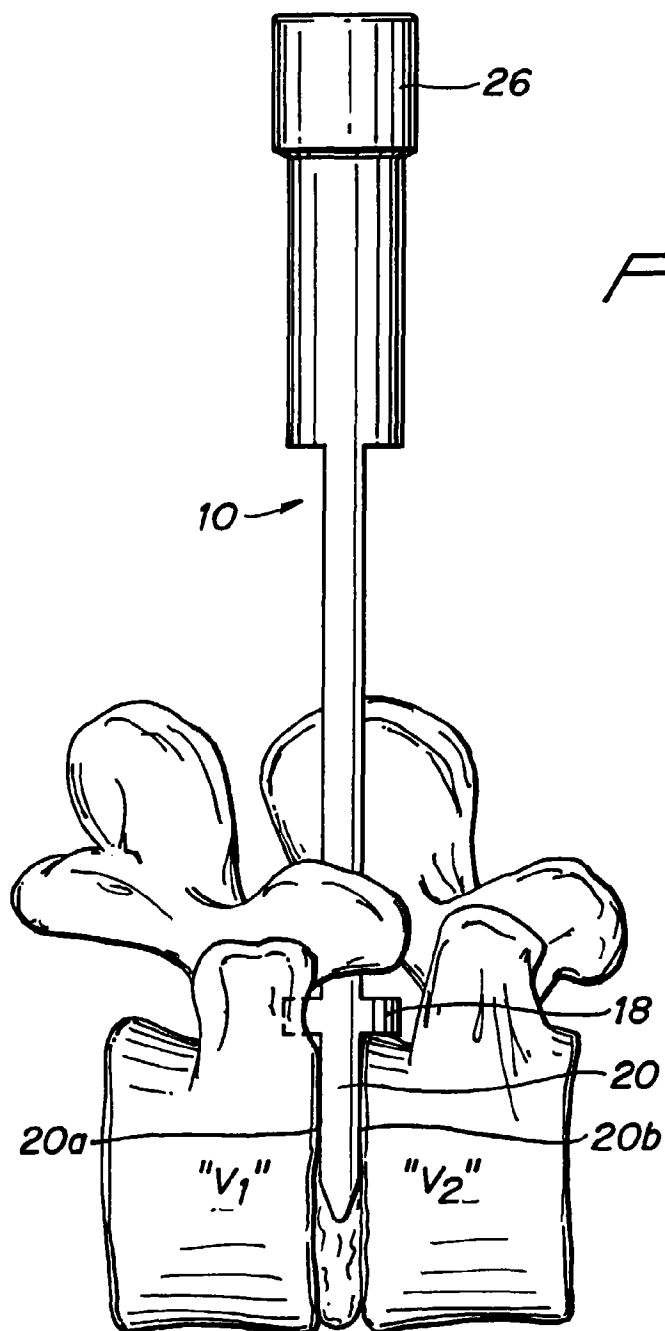
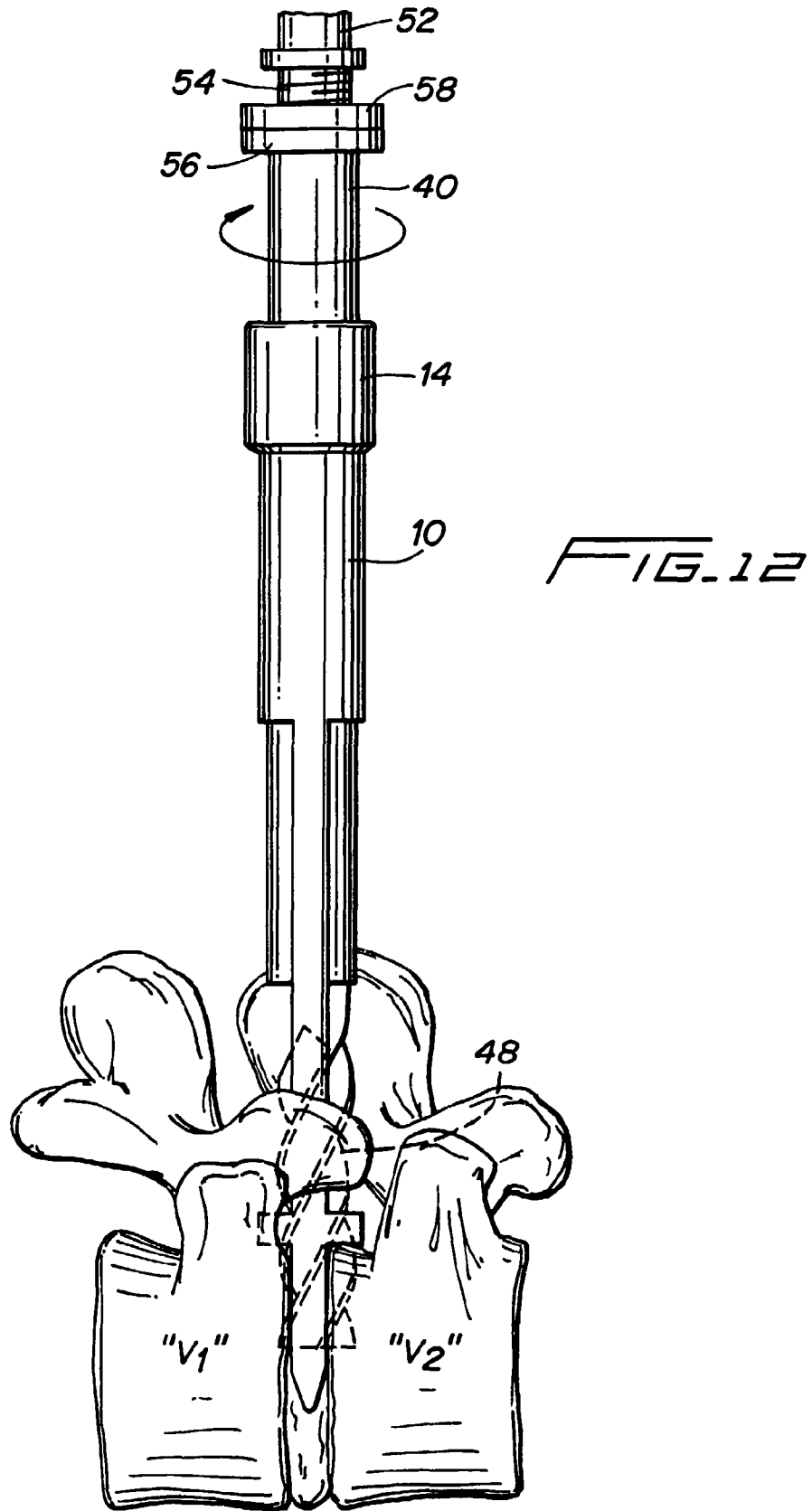
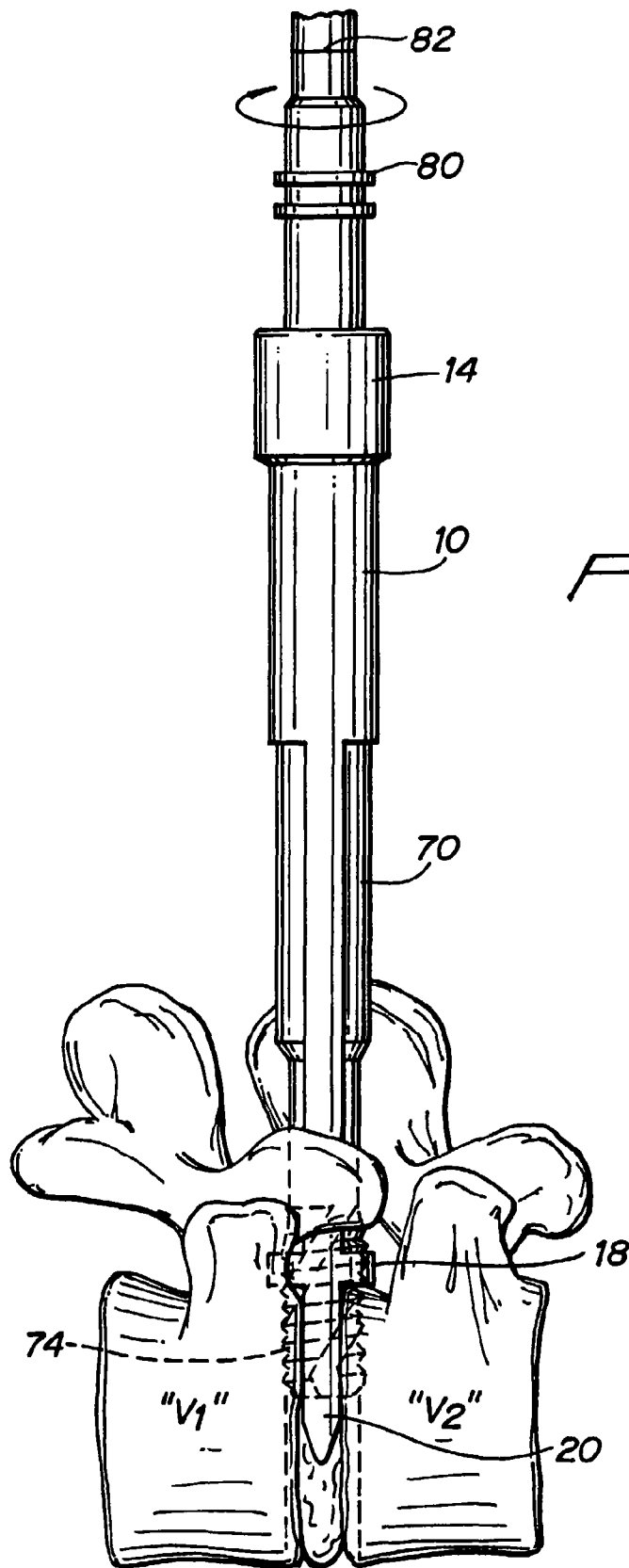
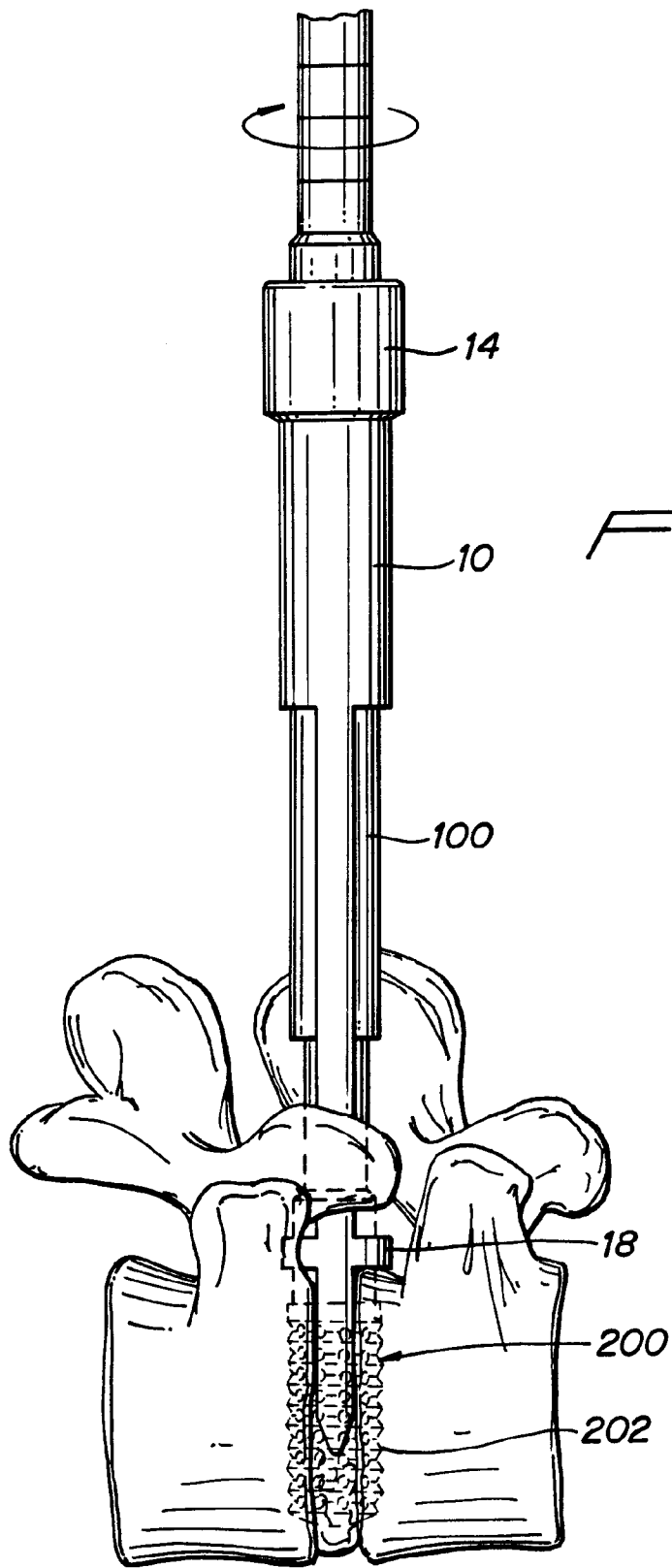


FIG. 10B









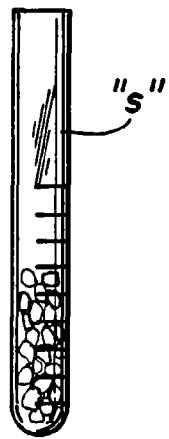


FIG. 15

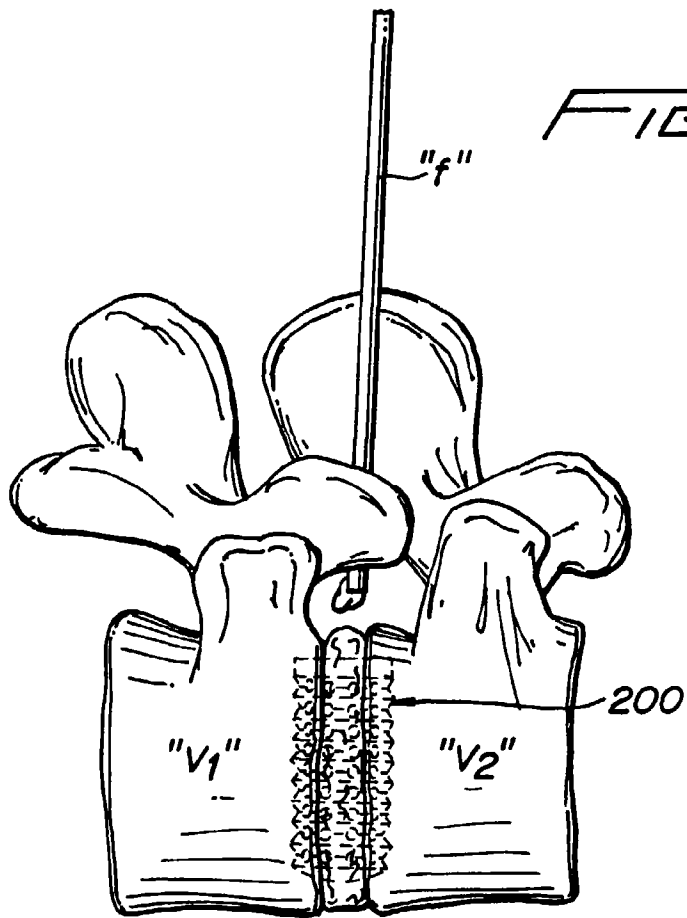
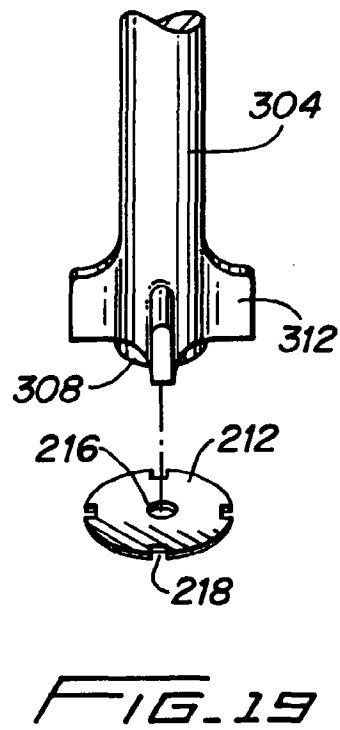
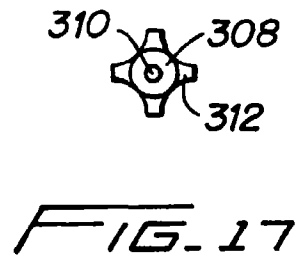
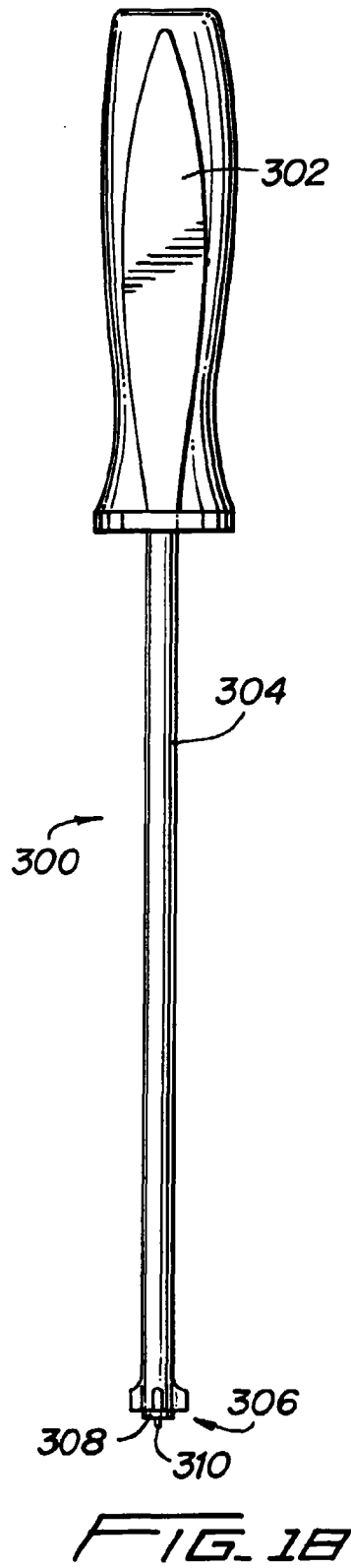


FIG. 16



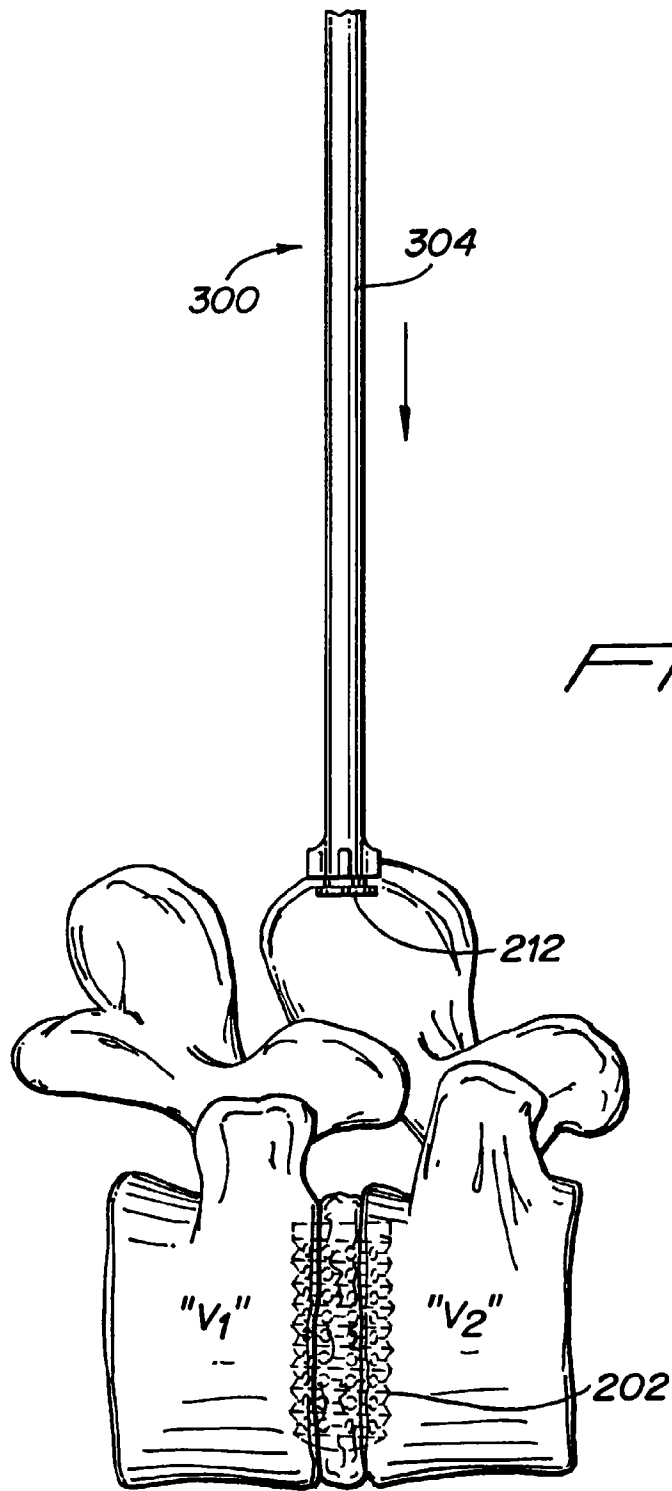
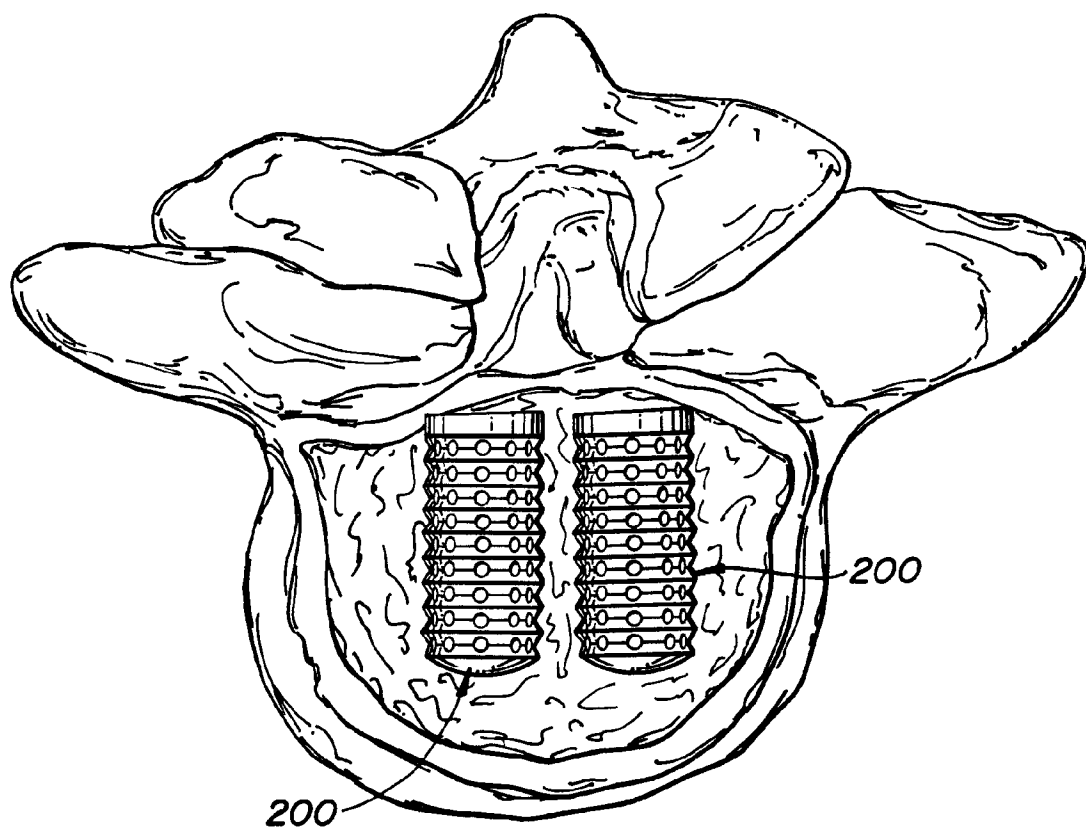


FIG. 21



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(54) Instrumentation for implant insertion

(57) A surgical retractor instrument includes at least two elongate members disposed in side by side relation. Each elongate member has proximal and distal end portions and defines a longitudinal passageway for reception of surgical instrumentation. The distal end portion of each elongated member is configured for insertion at least partially within a space defined between adjacent

tissue portions, preferably, adjacent vertebrae. The distal end portion includes at least two retractor arms extending in a general longitudinal direction. Each retractor arm has first and second supporting surfaces for engaging opposed adjacent tissue portions, and defines a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof.

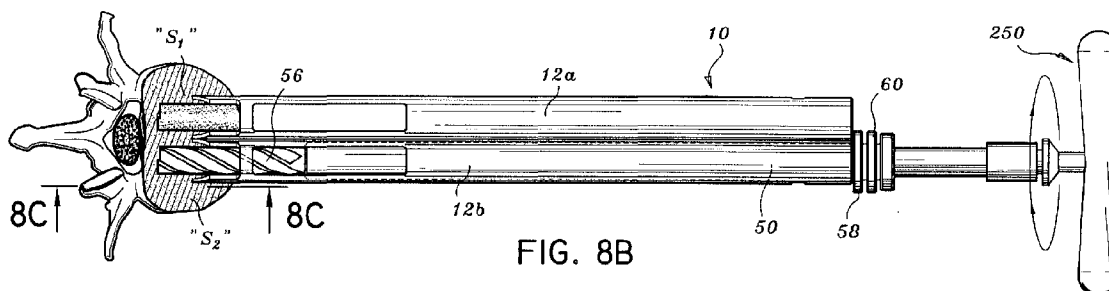
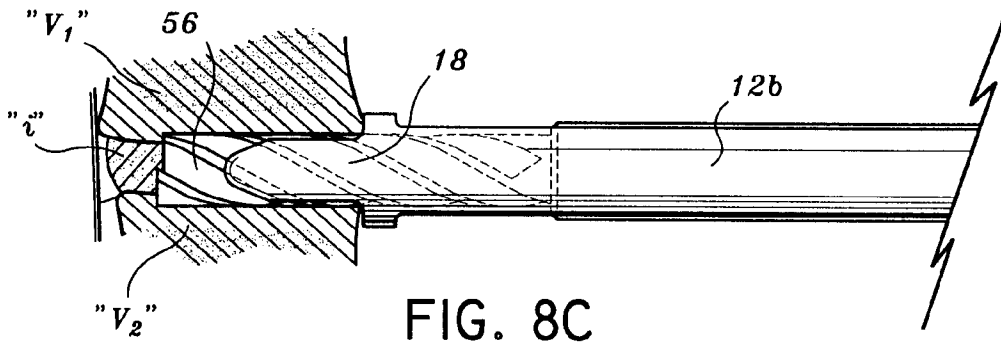


FIG. 8B

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Description

BACKGROUND

1. Technical Field

The present disclosure generally relates to a method and associated instrumentation for implant insertion and, in particular, to a method and instrumentation for insertion of a pair of spinal implants to facilitate fusion of adjacent vertebral bodies.

2. Background of the Related Art

A large number of orthopedic procedures involve the insertion of either natural or prosthetic implants into bone or associated tissues. These procedures include, for example, ligament repair, joint repair or replacement, non-union fractures, facial reconstruction, spinal stabilization and spinal fusion. In a typical procedure, an insert, dowel or screw is inserted into a prepared bore formed in the bone or tissues to facilitate repair and healing. See, for example, U.S. Patent Nos.: 5,470,334 to Ross et al.; 5,454,811 to Huebner; 5,480,403 to Lee et al.; 5,358,511 to Gattorna et al.; and 4,877,020 to Vich.

Some implants are particularly configured with cavities and bores to facilitate bony ingrowth and enhance anchoring of the implant at the insertion site. See, for example, U.S. Patent Nos.: 4,328,593 to Sutter et al.; 4,936,851 to Fox et al.; and 4,878,915 to Brantigan. Other specialized implants include fusion cages having internal cavities to receive bone growth stimulation materials such as bone chips and fragments. See, for example, U.S. Patent Nos.: 4,501,269 to Bagby; 4,961,740 to Ray et al.; 5,015,247 to Michelson; and 5,489,307 to Kuslich et al. These types of implants are particularly well suited for intervertebral spinal fusion procedures necessitated by injury, disease or some degenerative disorder of the spinal disc. Subsequently, there may be progressive degeneration leading to mechanical instability between adjacent vertebrae necessitating direct fusion of the vertebrae while maintaining a pre-defined intervertebral space. This fusion may be accomplished by the insertion of one or more of the specialized implants as discussed above and also discussed U.S. Patent No. 5,026,373, the contents of which are incorporated herein by reference.

Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar spine. Fusions in the cervical area of the spine are primarily performed using posterior and anterior approaches as well. Typically, an implant such as a plug, dowel, prosthesis or cage is inserted into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these procedures to promote a "bone to bone" bridge, connective tissue and at least a portion of the distal tissue is removed. Preferably, relatively deep cuts are made in the adjacent bones in order to pene-

trate into the softer, more vascularized cancellous region to facilitate bone growth across the implant.

One of the more critical tasks performed in the insertion of a surgical fusion implant, particularly, in intervertebral spinal fusion, is the formation of the implant receiving cavity or bore within the adjacent vertebrae. More particularly, the drilled bore must be equally centered within the intervertebral space and preferably parallel to the vertebral end plates to ensure removal of equal portions of bone from the adjacent vertebrae throughout the length of the cut and subsequent appropriate seating of the implant relative to the vertebral bodies.

Surgical instruments for facilitating spinal fusion implant insertion are known. For example, U.S. Patent No. 5,484,437 to Michelson discloses a method and apparatus incorporating an outer and an inner sleeve arrangement. The outer sleeve has teeth at one end which are driven directly into the posterior surface of the adjacent vertebrae. The inner sleeve is positioned within the outer sleeve and serves to guide instruments such as a drill used to form the implant receiving bore. U.S. Patent Nos.: 5,487,307 to Kuslich et al.; 5,015,247 to Michelson; and 4,878,915 to Brantigan disclose similar arrangements. Other arrangements include the use of guide rods which are placed in pilot holes formed in the vertebral bodies. The guide rods guide a bore forming hollow drill into the intervertebral space.

Although current instrumentation and methods associated therewith for enhancing the placement of spinal fusion implants have been generally effective for their intended purposes, there exists certain limitations with the design of this instrumentation which detract from their usefulness. For example, the arrangement disclosed in the Michelson '437 patent and similar arrangements do not provide for automatic alignment of the outer sleeve to ensure that the bore formed by a drill introduced into the outer sleeve is in optimal alignment for a tapping procedure (if required) and reception of the spinal implant. Rather, such orientation is dependent directly upon the skill of the surgeon. Moreover, the outer sleeve, which is mounted only at its extreme distal end to the posterior surface of the adjacent vertebrae, is subject to disorientation or dislodgment during insertion and/or removal of the drill and/or tapping instrument. Similarly, the use of guide rods increases the number of steps required to implant the fusion cage and is also subject to possible misalignment.

In many surgical implant techniques, two implants are inserted within the intervertebral space in side-by-side or lateral relation to fully support the adjacent vertebrae across the span of the intervertebral space. In accordance with these techniques, a first lateral side of the intervertebral space is prepared, e.g., by removing excess disc material and drilling/tapping a bore to receive the implant followed by insertion of the implant. Thereafter, the second lateral side is prepared for implant insertion in the same manner. During the initial

preparation of the first lateral side of the intervertebral space, however, the adjacent vertebrae are subjected to displacement in both the lateral and longitudinal direction. This may cause additional movement of the vertebral portion disposed on the other (second) lateral side of the intervertebral space.

U.S. Patent No. 5,489,307 to Kuslich discloses a surgical method for implanting two spinal implants into a disc space utilizing a distraction spacer which is inserted initially within one side of the intervertebral space. The rigid distraction spacer is intended to act against the vertebral end plates of the adjacent vertebrae to urge the vertebrae apart while the second side of the intervertebral space is prepared, by drilling/tapping, to receive an implant. Once the implant is inserted, the distraction spacer is removed and the side left unoccupied by removal of the spacer is prepared to receive the second implant.

The present disclosure is directed to a method and associated instrumentation to facilitate the introduction of at least two fusion implants, which maintains the desired disc height across the span of the intervertebral space and thereby ensures optimal alignment of each drilled bore for reception of the fusion implant.

SUMMARY

In one preferred embodiment, a surgical retractor instrument is disclosed. The retractor instrument includes at least two elongated members connected to each other in side by side relation. Each elongated member has proximal and distal end portions and defines a longitudinal passageway for reception of surgical instrumentation. The distal end portion of each elongated member is configured for insertion at least partially within a space defined between adjacent tissue portions. Preferably, the distal end portion of each elongated member includes at least one retractor arm extending in a general longitudinal direction. Each retractor arm has first and second supporting surfaces for engaging opposed adjacent tissue portions, and defines a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof. The first and second supporting surfaces of each retractor arm may be substantially planar. The retractor arms may be dimensioned between the first and second supporting surfaces to distract adjacent vertebrae. In an alternate embodiment two spaced apart retractor arms extend from the distal end portion of each elongated member.

In another preferred embodiment, a surgical retractor for use in distracting adjacent vertebrae includes first and second elongate sleeve members connected to each other in side by side relation. Each sleeve member has a proximal end and a distal end and defines a longitudinal passageway therebetween. At least two retractor arms extend longitudinally from the distal end of the retractor. Each retractor arm defines a first vertebra sup-

porting surface and a second vertebra supporting surface portion. The first and second vertebra supporting surfaces of each retractor arm are spaced thereon at a predetermined distraction distance.

In an alternate embodiment, a spacer member is disposed between the first and second sleeve members to space the sleeve members at a predetermined distance.

A method for performing a surgical procedure with the surgical retractor is also disclosed. The method includes the steps of providing a surgical retractor including at least two elongate members connected to each other along longitudinal portions thereof and having proximal and distal end portions with an opening there-through to receive instrumentation, the distal end portion of each elongate member configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae, inserting the distal end of the two elongate members of the retractor to distract lateral sides of the intervertebral space and performing the surgical procedure adjacent the distracted vertebrae. The distal end portion of at the retractor may include two spaced apart retractor arms having first and second supporting surfaces and wherein the step of distracting includes inserting the retractor arms within the intervertebral space whereby the first and second supporting surfaces of each retractor arm respectively engage the adjacent opposed vertebrae. Surgical instrumentation may be inserted within the opening of one of the elongate members to perform the surgical procedure. In a preferred embodiment, a fusion implant is inserted through the opening of the one elongate member and between the distracted vertebrae to effect fusion thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the disclosure are described hereinbelow with reference to the drawings wherein:

FIG. 1 illustrates a double surgical retractor constructed in accordance with the principles of the present disclosure and utilized in distracting adjacent bony structures, particularly adjacent vertebrae, and having first and second retractor sleeves; FIG. 2 is a top plan view of the double retractor of FIG. 1;

FIG. 3 is a side plan view of the double retractor; FIG. 4 is a cross-sectional view of the double retractor taken along the lines 4-4 of FIG. 3;

FIG. 5 is a perspective view of a surgical kit for performing a spinal fusion procedure illustrating, from bottom to top, the double retractor of FIG. 1, an implant insertion apparatus, a surgical tap instrument, a drill instrument and a T-shaped handle;

FIG. 6 is a view illustrating a portion of the vertebral column;

FIG. 7 is a side view illustrating insertion of the double retractor of FIG. 1 within an intervertebral space defined between adjacent vertebrae;

FIG. 8A is a view of the intervertebral space taken along the lines 8A-8A of FIG. 6 illustrating insertion of the drill instrument through a first retractor sleeve of the double retractor to drill a bore adjacent a first lateral side of the adjacent vertebrae;

FIG. 8B is a view similar to the view of FIG. 8A illustrating insertion of the drill instrument within the second retractor sleeve to drill a bore adjacent a second lateral side of the adjacent vertebrae;

FIG. 8C is a view taken along the lines 8C-8C of FIG. 8B further illustrating advancement of the drill instrument within the intervertebral space defined between adjacent vertebrae;

FIG. 9A is a view similar to the view of FIG. 8A illustrating insertion of the tap instrument within the first retractor sleeve for tapping the bore formed in the first lateral side of the adjacent vertebrae by the drill instrument;

FIG. 9B is a view similar to the view of FIG. 9A illustrating insertion of the tap instrument within the second retractor sleeve for tapping the bore formed in the second lateral side of the adjacent vertebrae by the drill instrument;

FIG. 10 is a view similar to the view of FIG. 8A illustrating insertion of the implant insertion instrument with mounted fusion implant within the retractor to mount the implant within the tapped bore;

FIG. 11 is a view taken along the lines 11-11 of FIG. 10 further illustrating insertion of the implant insertion instrument within the intervertebral space defined between adjacent vertebrae;

FIG. 12 is a cross-sectional view illustrating the insertion of two implants within the intervertebral space;

FIG. 13 is a perspective view of an alternate embodiment of the double surgical retractor of FIG. 1 having a spacing member interposed between the retractor sleeves to laterally displace the two retractor sleeves;

FIG. 14 is a top plan view of the double retractor of FIG. 13;

FIG. 15 is a view of the double retractor of FIG. 13 taken along the lines 15-15 of FIG. 14;

FIG. 16 is a top plan view of another alternate embodiment of the double surgical retractor having a curved engagement surface;

FIG. 17 is a perspective view of yet another alternate embodiment of the double surgical retractor having two retractor arms; and

FIG. 18 is a top plan view of the double surgical retractor of FIG. 17.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

The preferred embodiments of the method and instrumentation disclosed herein are discussed in terms of orthopedic spinal fusion procedures and instrumentation. It is also envisioned, however, that the disclosure is applicable to a wide variety of procedures including, but, not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and spinal stabilization. In addition, it is believed that the present method and instrumentation finds application in both open and minimally invasive procedures including endoscopic and arthroscopic procedures wherein access to the surgical site is achieved through a cannula or small incision.

The following discussion will include a description of each instrument utilized in performing a spinal fusion method followed by a description of the preferred method for spinal fusion utilizing the instrumentation in accordance with the present disclosure.

In the discussion which follows, the term "proximal", as is traditional, will refer to the portion of the structure which is closest to the operator, while the term "distal" will refer to the portion which is furthest from the operator.

Referring now to the drawings in which like reference numerals identify similar or identical elements throughout the several views, FIG. 1 illustrates in perspective view a preferred embodiment of the double surgical retractor of the present disclosure. Double retractor 10 is particularly contemplated for distracting adjacent bony structures, e.g., adjacent vertebral bodies, to facilitate the insertion and application of a pair of implants. However, it is envisioned that double retractor 10 may also be utilized to distract other structures as well including joints, ligaments, etc... Other applications for retractor 10 are also contemplated.

Referring now to FIGS. 1-2, double retractor 10 includes first and second retractor sleeves 12a, 12b connected to each other along adjacent peripheral portions as shown. Retractor sleeves 12a, 12b may be formed of any suitable rigid material including stainless steel, titanium, aluminum or a suitable polymeric material and formed by injection molded techniques. Retractor sleeves 12a, 12b may be two separate components connected to each other by conventional means including adhesives, welding or the like or may be a single monolithic unit.

Each retractor sleeve 12a, 12b is similar in configuration to the retractor sleeve disclosed in U.S. patent Application Serial No. 08/615,379, filed March 14, 1996, the contents of which are incorporated herein by reference. Each sleeve 12a, 12b may be a variety of sizes such as 12 mm, 14 mm, 16 mm and 18 mm in diameter. The retractor size utilized will generally correspond to the size of the fusion implant to be applied. As shown, each retractor sleeve 12a, 12b has a longitudinal pas-

sageway extending from the proximal to the distal end portion to receive surgical instrumentation therethrough to carry out the fusion procedure.

With reference now to FIGS. 1-4, each sleeve 12a, 12b may optionally include first and second longitudinally extending openings 14 formed in its outer wall. Openings 14 are diametrically arranged with relation to each other and terminate at their distal ends in circumferential collar 16. Each opening 14 preferably extends radially for about between 15%-40% the circumference or perimeter of sleeve 12a, 12b and longitudinally preferably for about 25% the length of sleeve 12a, 12b. Openings 14 are contemplated to permit the introduction of surgical instrumentation if necessary to assist in carrying out the fusion procedure.

Each sleeve 12a, 12b further includes first and second diametrically opposed retractor arms 18. Retractor arms 18 extend distally from collar 16 in a general longitudinal direction and are spaced from each other. Each arm 18 has an arcuate outer surface (i.e., defining a radius of curvature substantially equivalent to the radius of curvature of the remaining portion of the sleeve). Each retractor arm 18 has first and second supporting surfaces 18a, 18b in general parallel relation to each other and preferably to the longitudinal axes "a" of each sleeve 12a, 12b. The supporting surfaces 18a, 18b are preferably substantially planar. The height "h" of each arm 18 (i.e., the distance between supporting surfaces 18a, 18b) corresponds to the height of the space between adjacent bony structures to be distracted. For example, in spinal fusion application, the height "h" of each arm 18 preferably ranges from about 0.28 to about 0.35 inches. Each arm 18 further includes tapered end portions 20 defining a generally V-shaped configuration. End portions 20 facilitate insertion of retractor arms 18 within the surgical site, e.g., within the intervertebral space.

As depicted in FIG. 5, retractor 10 may further include impactor head 22 which is correspondingly dimensioned to fit over the proximal ends of retractor sleeves 12a, 12b. Impactor head 22 is dimensioned to slide onto retractor 10 and form a friction fit therebetween. Impactor head 22 may further include an inner shelf which engages the proximal end faces of retractor sleeves 12a, 12b. In the alternative, impactor head 22 may be closed at its proximal end.

Referring still to FIG. 5, the various instruments utilized in performing a double spinal fusion procedure with the retractor 10 of the present disclosure are illustrated. These instruments include surgical drill 50, tap instrument 100, implant insertion instrument 150, fusion implant 200 and T-shaped handle 250 which is used to actuate each of the instruments.

Surgical drill 50 is disclosed in the previously incorporated '379 application. Drill 50 includes drill shaft 52, extension shaft 54 and drill bit 56 mounted at the distal end of the drill shaft 52. Extension shaft 54 has first and second collars 58, 60 which cooperate to control the

depth of penetration of drill shaft 52 and drill bit 56 into the adjacent vertebrae. Drill shaft 52 includes a hexagonal-shaped head 62 at its proximal end to mount T-handle 250.

Tap instrument 100 is also disclosed in the '379 application. Tap instrument 100 is utilized for forming an internal thread within the drilled bore formed by the drill instrument 50. Tap instrument 100 includes elongated member 102 having hex head 104 at its proximal end to engage T-shaped handle 250. Tap instrument 100 further includes distal tapping threaded portion 106. Distal tapping portion 106 includes a plurality of conveyance channels (one is shown) 108 extending longitudinally through the cutting thread. Each conveyance channel 108 has a directional component parallel to the longitudinal axis and a directional component transverse to the longitudinal axis. Each conveyance channel 108 encompasses approximately an arc of about 1/3 the outer circumference of the tapping portion 106. Conveyance channels 108 are each dimensioned to receive bone material deburred by the cutting edges during the tapping procedure and to continually transmit the bone material proximally through the channel to avoid undesired material build up at the tapping site. In this manner, tap instrument 100 may be used to completely tap the internal thread within the bore without interruption of the tapping procedure.

Implant insertion instrument 150 is configured for mounting and inserting fusion implant 200 within the intervertebral space. Insertion instrument 150 includes elongated shaft 152 having hex-head mounting section 154 at its proximal end and cylindrical collar 156 at its distal end. Cylindrical collar 156 is dimensioned to be received within the cavity of fusion implant 200. A spring ball detent mechanism 158 is disposed within cylindrical collar 156 to releasably engage implant 200. Detent mechanism 158 is preferably spring-biased outwardly to engage corresponding structure defined within fusion implant 200 such as a recess or aperture formed in an interior wall thereof. Any type of detent mechanism 158 suitable for this intended purpose may be utilized. Collar 156 may further include a pair of longitudinal grooves 160 which engage corresponding structure of implant 200 (e.g., inner longitudinal rails) to rotatably fix the implant on the collar, i.e., to prevent rotational movement of the implant 200 on the collar. Other insertion instruments and arrangements are also envisioned.

Implant 200 is uniquely designed for use in spinal fusion procedures. This implant 200 is generally disclosed in U.S. Patent No. 5,026,373 to Ray, the contents of which have been previously incorporated herein by reference, and is commonly referred to as a "fusion cage". Implant or fusion cage 200 includes a cylindrical cage body 202 having an internal cavity or hole for accommodating bone-growth inducing substances. One end of cage body 202 is closed and defines a rounded or bull-nosed configuration to facilitate insertion of the fusion cage relative to one or more bony structures. The

other end defines an opening which communicates with the internal cavity. The outer surface of the cage body 202 includes a single continuous thread (preferably V-shaped) having a plurality of raised turns with valleys defined between adjacent turns.

A plurality of perforations are disposed within the thread and extend through the outer surface of the cage body 202 to provide direct communication between the outer surface and internal cavity. The perforations permit immediate contact between the bone growth inducing substances within the inner cavity and the bone structure when the cage body 202 is mated to the bone structure, e.g., adjacent vertebrae. An end cap (not shown) may be mountable to the open end of cage body 202 to enclose the bone-growth inducing substances within the interior cavity.

T-shaped handle 250 includes mounting portion 252 defining hexagonal-shaped recess 254 which receives the corresponding structure of drill instrument 50, tap instrument 100 and implant insertion instrument 150.

Operation of the Instrumentation

The use of the instrumentation in conjunction with the insertion of a pair of fusion implants 200 into an intervertebral space defined between adjacent vertebrae will be described. The subsequent description will be particularly focused on an anterior procedure for spinal surgery although a posterior approach is envisioned as well.

With reference to FIG. 6, which depicts a portion of the vertebral column, a targeted intervertebral space "i" defined between adjacent vertebrae "V₁, V₂" is accessed utilizing appropriate retractors, e.g., laminar retractors, dural extractors.

As depicted in FIG. 7, impactor head 22 is placed on the proximal end of retractor sleeves 12a, 12b. Retractor 10 is manipulated to align retractor arms 18 within the desired intervertebral space "i" defined between adjacent vertebrae "V₁, V₂". Preferably, retractor 10 is arranged such that retractor sleeve 12a is adjacent a first lateral side "S₁" of the intervertebral space "i" and retractor sleeve 12b is adjacent a second lateral side "S₂" of the intervertebral space "i". Thereafter, retractor arms 18 are advanced into the intervertebral space "i" whereby first and second supporting surfaces 18a, 18b of each retractor arm 18 respectively engage the opposed vertebral bodies "V₁, V₂". Retractor arms 18 are preferably dimensioned to slightly distract the adjacent vertebrae "V₁, V₂". However, alternatively, it is envisioned that retractor arms 18 may be configured to cause no distracting movement of the vertebrae "V₁, V₂". Once inserted, retractor arms 18 effectively stabilize the adjacent vertebrae "V₁, V₂" across the span of the intervertebral space "i". Preferably, during insertion, retractor 10 is driven distally, by e.g., impacting impactor head 22 with a standard mallet "m" as depicted in FIG.

7, which thereby drives retractor arms 18 within the adjacent vertebrae "V₁, V₂". Tapered end portions 20 of retractor arms 18 facilitate advancement within the intervertebral space "i".

Referring now to FIG. 8A, with retractor arms 18 of retractor sleeves 12a, 12b in their appropriate positions within the intervertebral space "i", attention is directed to drilling a bore in the first lateral side "S₁" of the intervertebral space "i". The cutting depth of drill instrument 50 is adjusted as desired (i.e., to correspond to the length of the fusion implant) by adjusting collars 58, 60. With the T-handle 250 mounted to drill instrument 50, the instrument is introduced into the axial bore of retractor sleeves 12a and advanced to contact the anterior surface of the vertebral bodies, "V₁, V₂". Drill 50 is advanced into the intervertebral space "i" adjacent the first lateral side "S₁" by rotating T-handle 250 such that drill bit 56 shears the soft tissue and cuts the bone of the adjacent vertebrae "V₁, V₂" thereby forming a bore which extends into the adjacent vertebrae "V₁, V₂". Drill 50 is then removed from retractor sleeve 12a. The drilling procedure is then repeated by insertion of drill instrument 50 within the second retractor sleeve 12b to form a bore within the adjacent vertebra "V₁, V₂" proximate the second lateral side "S₂" as depicted in FIGS. 8B-8C.

Referring now to FIG. 9A, tap instrument 100 is selected and attached to the T-handle 250. Tap instrument 100 is inserted into first retractor sleeve 12a and positioned adjacent the drilled bore formed in the adjacent vertebrae "V₁, V₂" by the surgical drill 50. With retractor sleeve 12a as a direct guide, T-handle 250 is rotated in the direction of the directional arrow of FIG. 9A while simultaneously applying sufficient downward pressure on the T-handle to advance the tap instrument 100 and promote even purchase into the endplates. Upon advancement of the tap instrument 100, the deburred bone chips collect within conveyance channel 108 of tapping head 106, and are conveyed proximally during rotational movement of the tapping head 106 away from the tapping site. Tap instrument 100 is advanced into the bone until the desired depth has been achieved, which occurs when the distal end of tapping head 108 "bottoms out" on the bone. When tap instrument 100 reaches the appropriate depth, the tap instrument 100 is rotated via T-handle 250 in an opposite direction to back the instrument out of the bore. The tapping procedure is then repeated by insertion of tap instrument 100 within the second retractor sleeve 12b to form a bore within the adjacent vertebrae "V₁, V₂" proximate the second lateral side as depicted in FIG. 9B. It is to be appreciated that in procedures where a self-tapping implant is utilized the tapping of the bores with tap instrument 100 is not necessary.

With reference now to FIG. 10, attention is focused on the insertion of fusion implant 200. FIG. 10 shows a first fusion implant 10 already applied within the bore proximate the first lateral side "S₁" of the intervertebral

space i. To apply the fusion implant, cage body 202 of the fusion implant 200 is mounted onto insertion instrument 150 by positioning the cage body 202 onto mounting collar 156 of the instrument to permit spring ball detent mechanism 158 to releasably engage corresponding structure of the implant body 202. This assembly is attached to T-handle 250. Insertion instrument 150 with mounted cage body 202 is inserted into retractor sleeve 12b of retractor 10 and the cage body 202 is positioned within the tapped bore by rotating insertion instrument 150 in the direction depicted in FIG. 10. Cage body 202 is advanced until it is completely seated with the bore as shown in FIG. 11. Insertion instrument 600 is then removed from retractor 100.

At this point in the procedure, bone growth inducing substances may be harvested from, e.g., the iliac crest, and packed into the cage body 202 of implant 200 until the cage body 202 is completely filled with bone growth inducing substances. An end cap may then be mounted to the cage body 202. Retractor 10 is then removed. It is also contemplated that the implant could be at least partially packed with bone growth inducing substances prior to insertion.

FIG. 12 illustrates the two lateral fusion implants 200 inserted within the intervertebral space in accordance with the afore-described procedure.

Thus, retractor 10 of the present disclosure maintains a desired spacing between the adjacent vertebra "V₁, V₂" across the lateral span of the intervertebral space during the entire spinal fusion procedure to facilitate insertion of the two implants 200. With the double sleeve arrangement 12a, 12b, additional retracting movement of the adjacent vertebra "V₁, V₂" is not required for drilling/tapping procedures and during insertion of the pair of implants 200. Moreover, the double sleeve arrangement ensures optical alignment of each drilled bore and placement of the two fusion implants 200. The double sleeve arrangement also reduces operating time since insertion of a separate retractor and/or distraction spacer is not required.

Referring now to FIGS. 13-15, an alternate embodiment of the surgical retractor 10 of the present disclosure is illustrated. This retractor is similar to the retractor disclosed in connection with FIG. 1 except for the rib or spacer 24 between first and second retractor sleeves 12a, 12b. Rib 24, interposed between retractor sleeves 12a, 12b, is dimensioned to increase the lateral spacing of retractor sleeves 12a, 12b and arms 18. An increase in the lateral spacing of sleeves 12a, 12b may be desirable to correspond to the size of the vertebrae targeted during the procedure. Moreover, an increase in lateral spacing, in effect, displaces the location of the pair of implants. Although shown as one single rib extending substantially the lengths of retractor sleeves 12a, 12b, connecting rib 24 may extend for only a portion of the length of retractor 10. Several connecting ribs 24 may alternatively be provided as well. In a preferred embodiment, connecting rib 24 is integrally formed with retract-

tor sleeves 12a, 12b as a single monolithic unit although it is envisioned that the rib 24 may be a separate component connected to each sleeve 12a, 12b by welding, adhesives, etc...

FIG. 16 illustrates an alternate embodiment of the double surgical retractor of the present disclosure. Double retractor 10' is identical to retractor 10 of Figure 1 except that surfaces 70a, 70b of each retractor sleeve 12a', 12b' are curved to better conform to the curvature of the anterior aspect of the vertebral body.

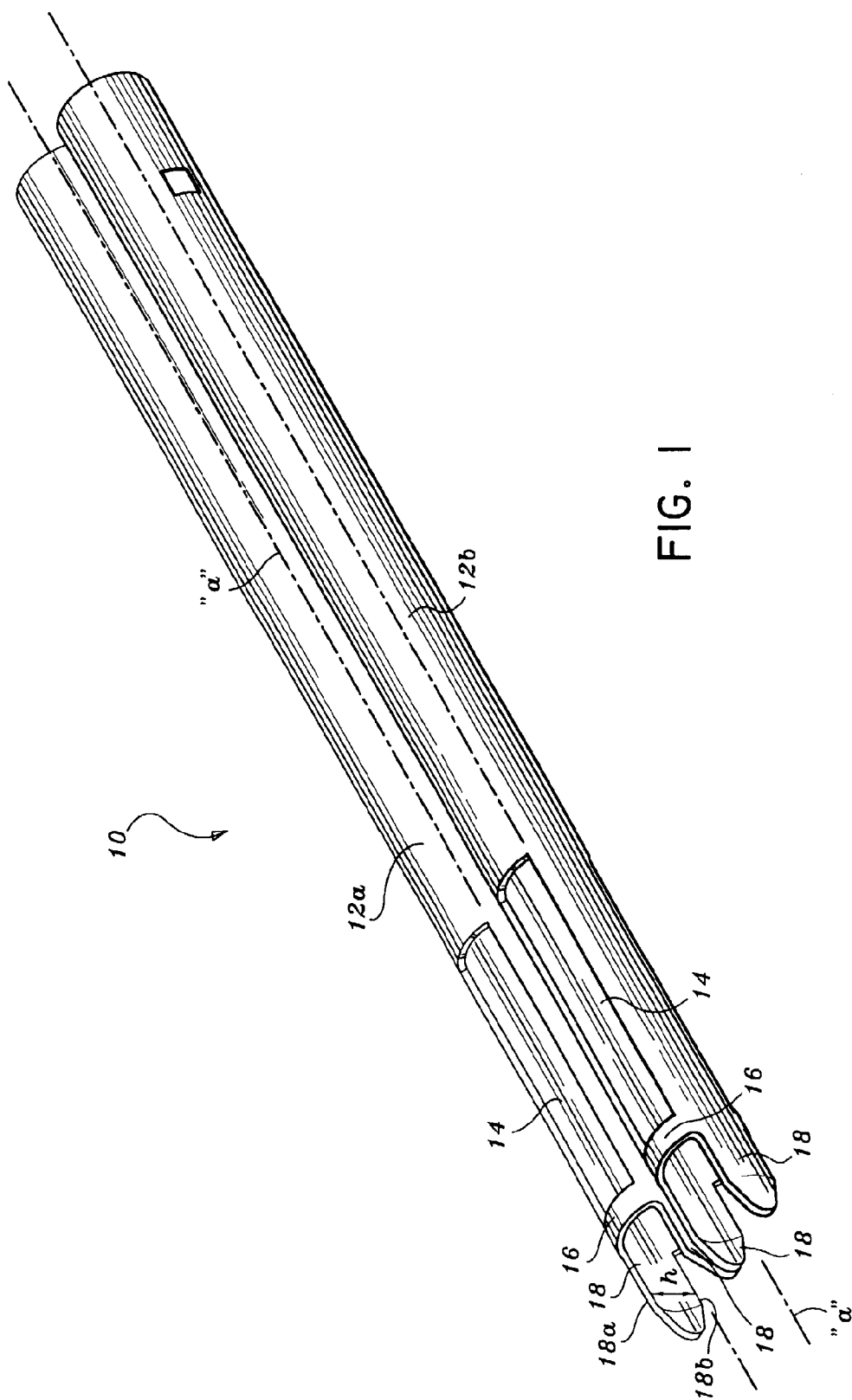
Another alternate embodiment of the surgical double retractor is illustrated in FIG. 17 and designated by reference numeral 80. Retractor 80 has two sleeves 82a and 82b. It differs from the other embodiments in that each sleeve 82a, 82b has only one retractor arm 84a, 84b, respectively. That is, the two central adjacent arms are eliminated, thereby reducing the extent of the anterior ligament removed during retractor insertion. Retractor 80 otherwise functions in the same manner as retractor 10 with each sleeve providing a cannula for insertion of the aforescribed instrumentation and arms 84a, 84b providing vertebral distraction. As shown in FIG. 18, retractor 80 preferably has a concave surface 80b to complement the natural shape of the vertebral body.

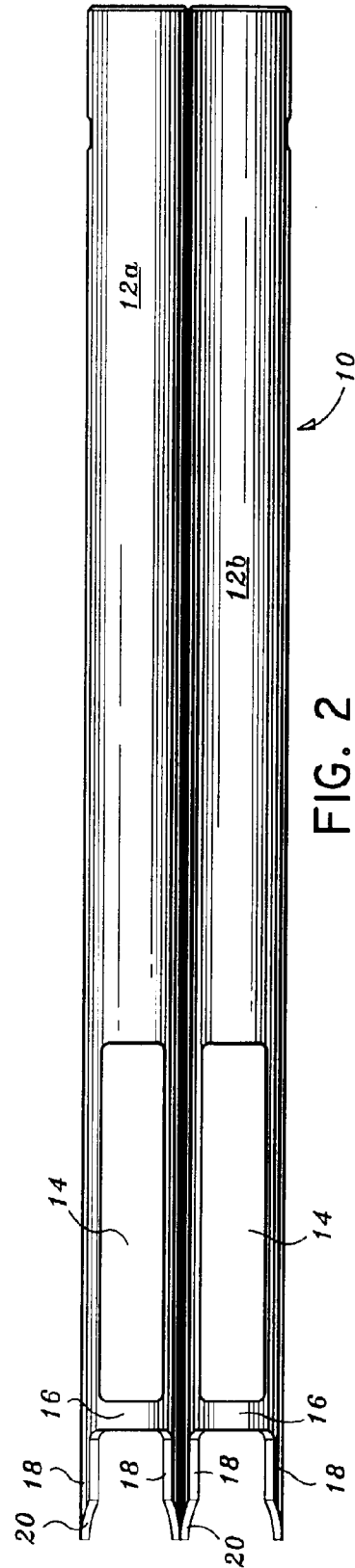
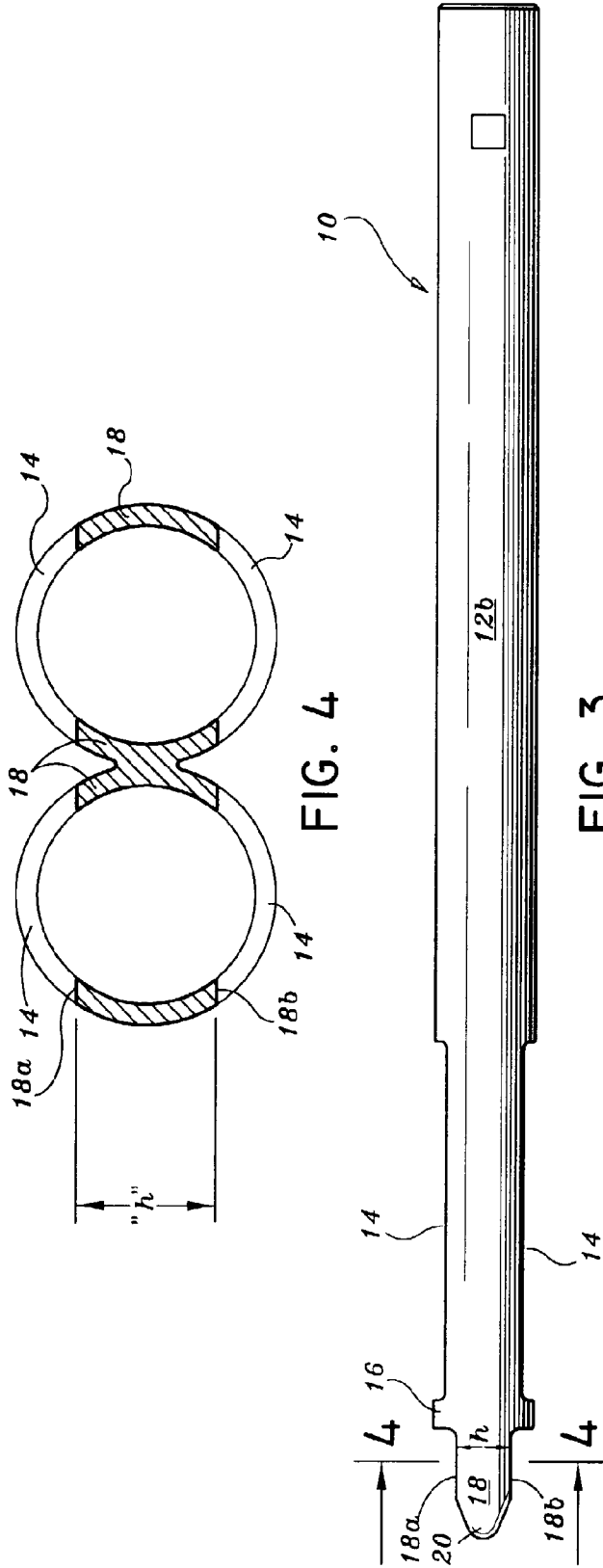
The claims which follow identify embodiments of the invention additional to those described in detail above.

Claims

1. A surgical retractor instrument comprising two elongate members disposed in side by side relation, each elongate member having proximal and distal end portions and defining a longitudinal passageway for reception of surgical instrumentation, the distal end portion of each elongate member configured for insertion at least partially within a space defined between adjacent tissue portions.
2. The surgical retractor according to claim 1 wherein the distal end portion of each elongate member includes at least one retractor arm extending in a general longitudinal direction, each retractor arm having first and second supporting surfaces for engaging opposed adjacent tissue portion, each retractor arm defining a dimension between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon insertion thereof.
3. The surgical retractor according to claim 2 wherein the dimension defined between the first and second supporting surfaces of each retractor arm is sufficient to distract adjacent vertebrae.
4. The surgical retractor according to claim 1, 2 or 3 wherein the first and second supporting surfaces of each retractor arm are substantially planar.

5. The surgical retractor according to any one of the preceding claims, wherein each retractor arm has a tapered end portion for facilitating insertion between the tissue portions. 5
6. The surgical retractor according to any one of the preceding claims, wherein the distal end portion of each elongate member has two retractor arms. 10
7. The surgical retractor according to any one of the preceding claims, wherein the two elongate members are monolithically formed. 15
8. The surgical retractor according to any one of the preceding claims, wherein the two elongated members are welded to each other. 20
9. A surgical retractor for use in distracting adjacent vertebrae comprising first and second elongate sleeve members arranged in side by side relation, each sleeve member having a proximal end and a distal end portion and defining a longitudinal passageway therebetween and at least one retractor arm extending longitudinally from the distal end portion of each sleeve member, each retractor arm defining a first vertebra supporting surface and a second vertebra supporting surface, the first and second vertebra supporting surfaces of each retractor arm being spaced thereon at a predetermined distraction distance. 25 30
10. The surgical retractor according to claim 9 wherein the distal end of each elongated member has two retractor arms, each arm having distal tapered portions for facilitating insertion. 35
11. The surgical retractor according to claim 9 wherein the retractor arms each possess distal tapered portions for facilitating insertion into the intervertebral space. 40
12. The surgical retractor according to claim 9, 10 or 11 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation. 45
13. The surgical retractor according to claim 12 wherein the first and second supporting surfaces of each retractor arm are in general parallel relation to the longitudinal axis of the elongate body. 50
14. The surgical retractor according to any one of claims 9 to 13 wherein each sleeve member includes at least one longitudinal opening defined in an intermediate wall portion thereof for reception of surgical instrumentation. 55
15. The surgical retractor according to any one of claims 9 to 14 wherein a distal surface of each sleeve member is concave.
16. The surgical retractor according to any one of claims 9 to 15 including a spacer member disposed between the first and second sleeve members to increase the distance between the sleeve members.
17. The surgical retractor according to any one of claims 9 to 16 wherein the first and second sleeve members are welded to each other.
18. The surgical retractor according to any one of claims 9 to 17 wherein the first and second sleeve members are monolithically formed.





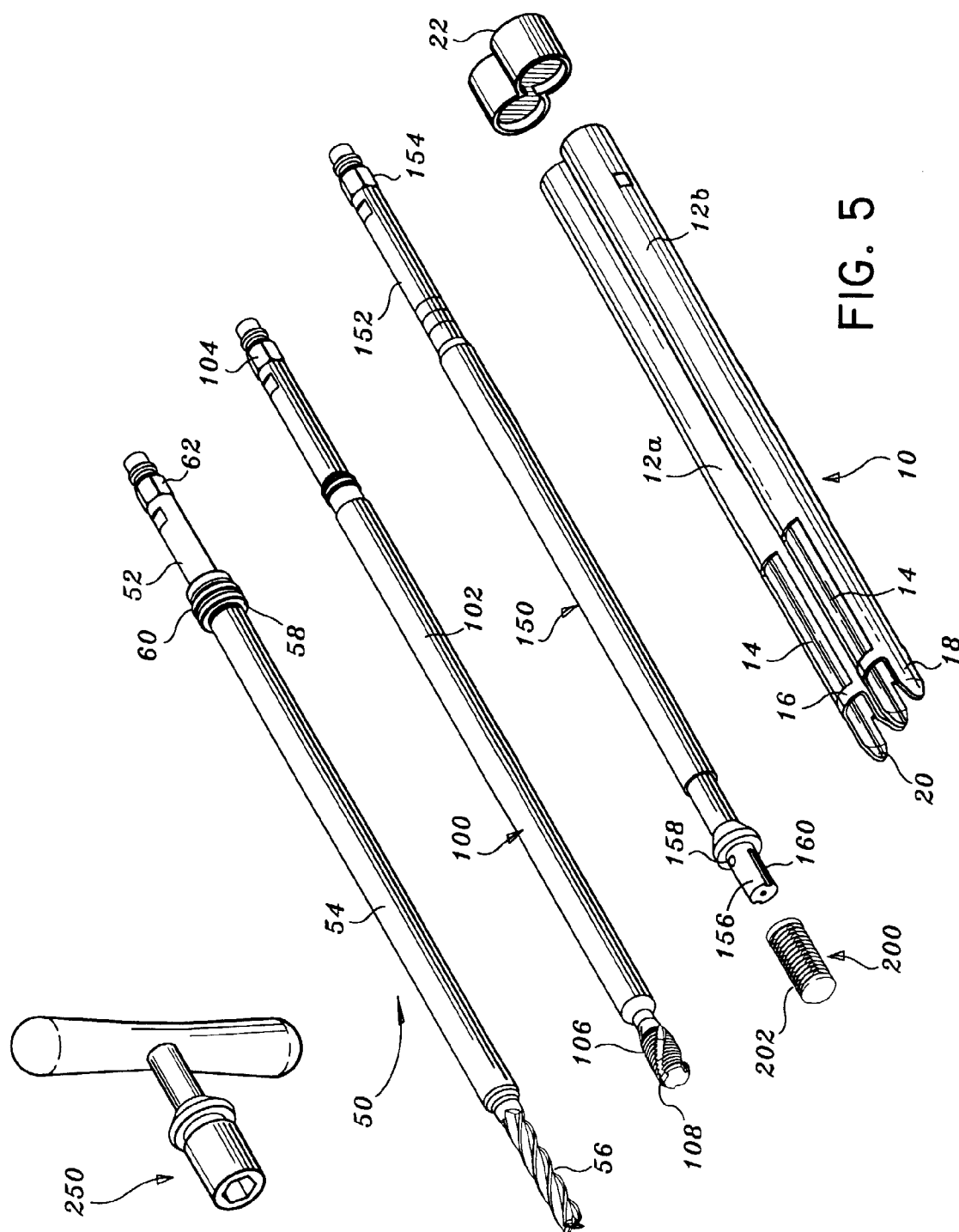


FIG. 5

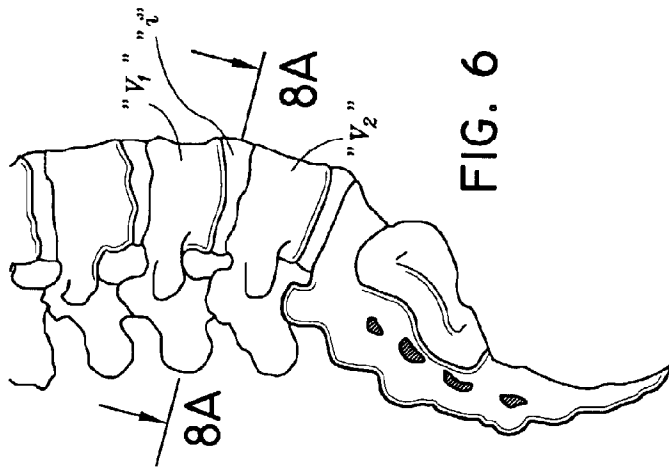


FIG. 6

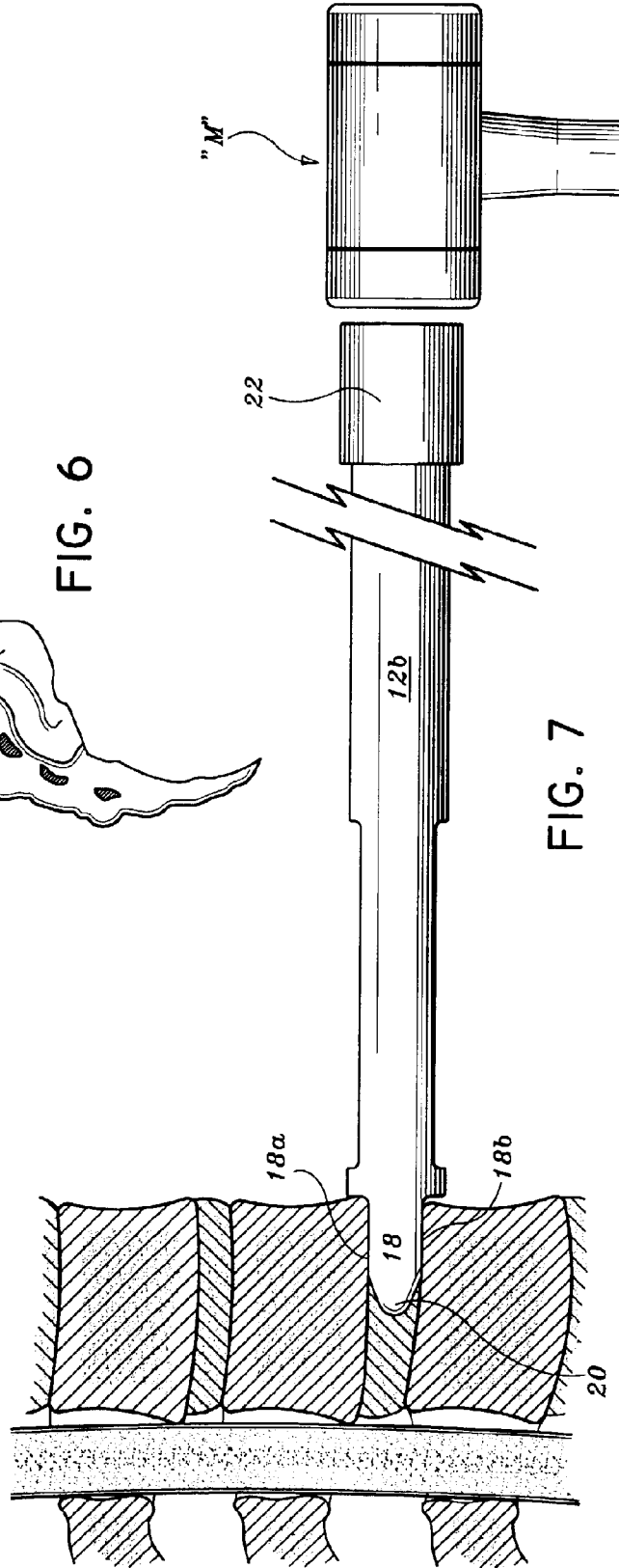
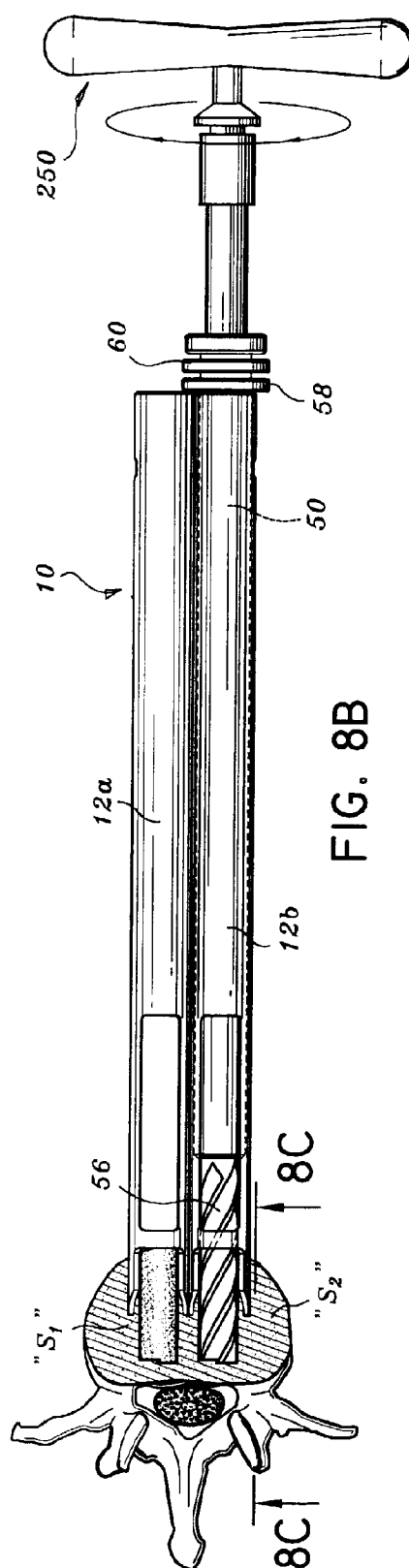
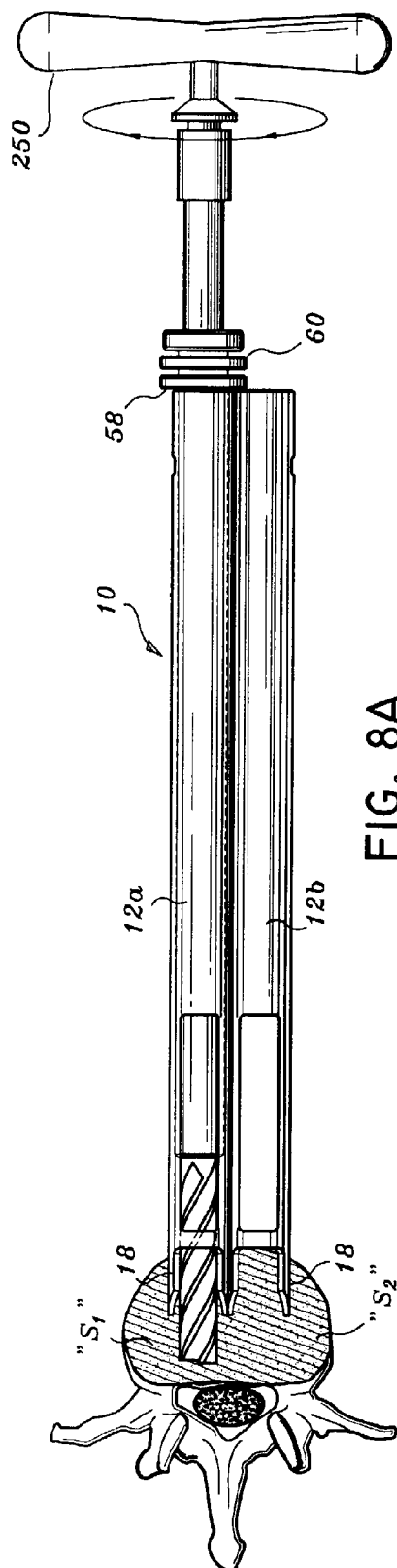


FIG. 7



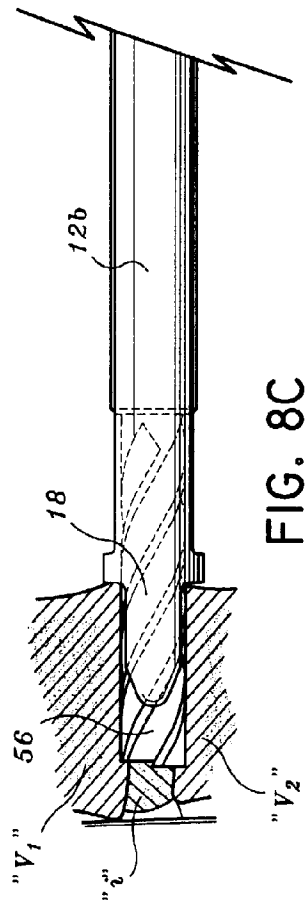


FIG. 8C

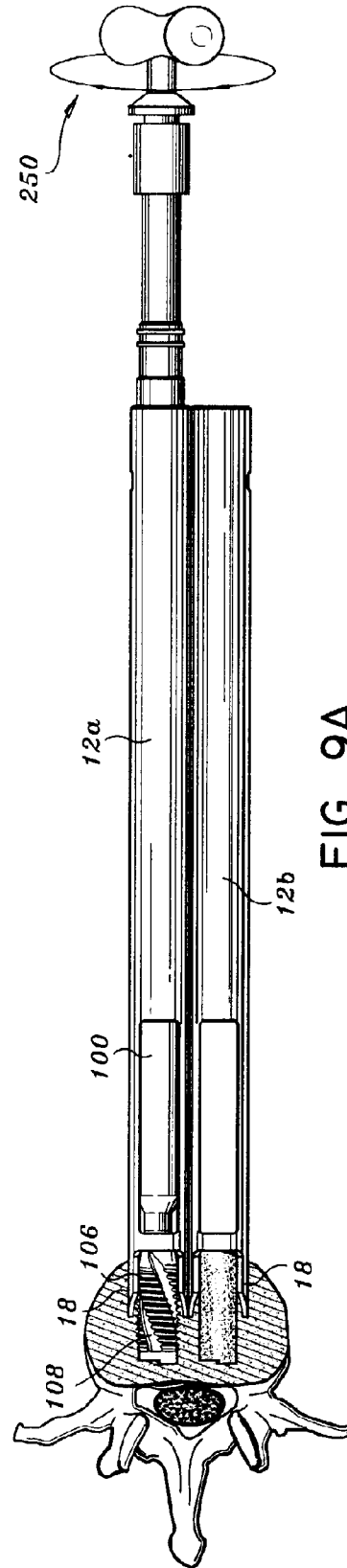
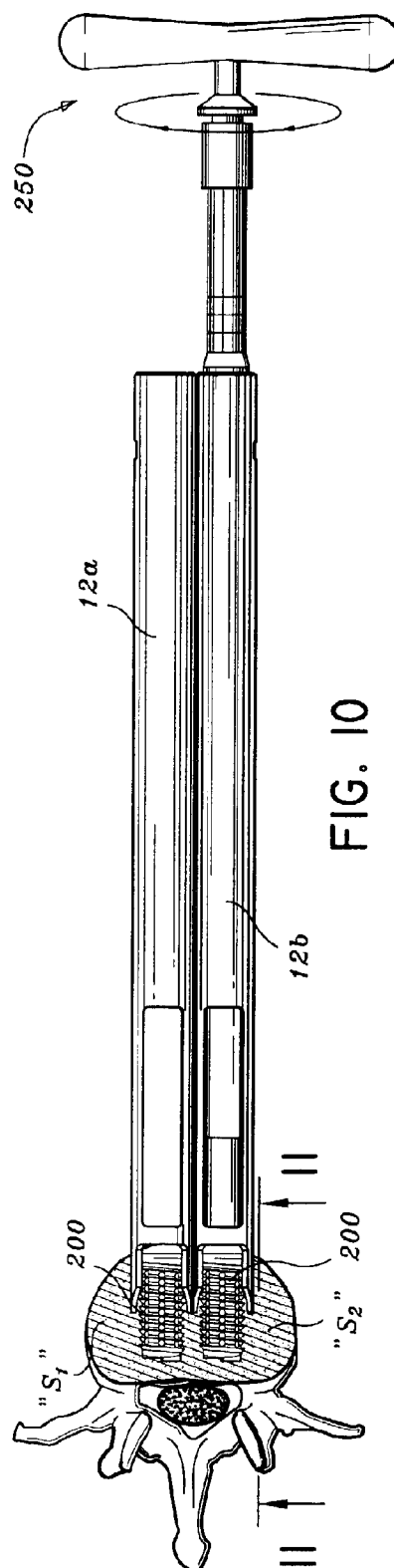
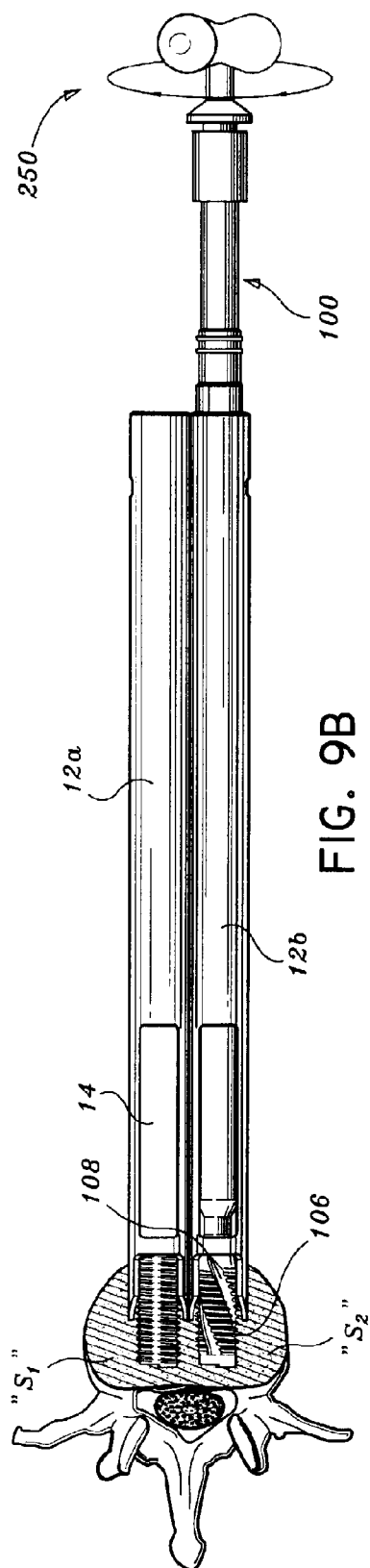
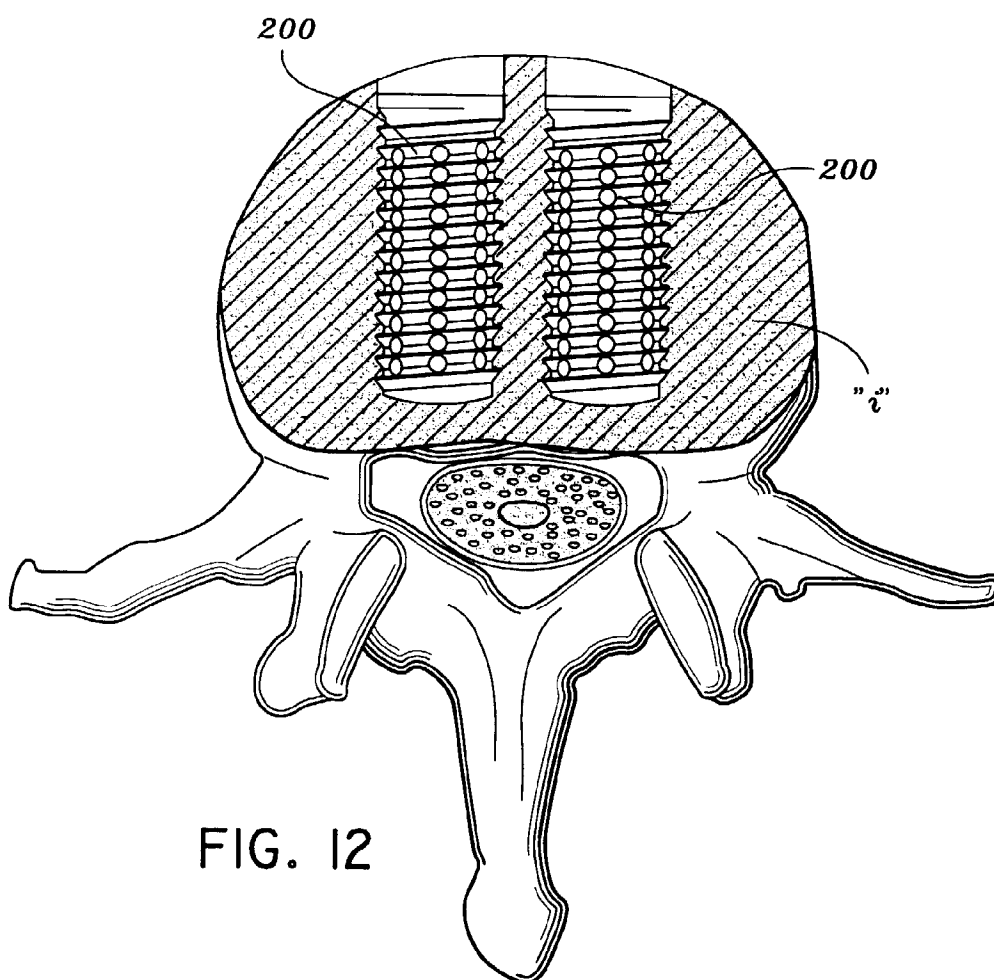
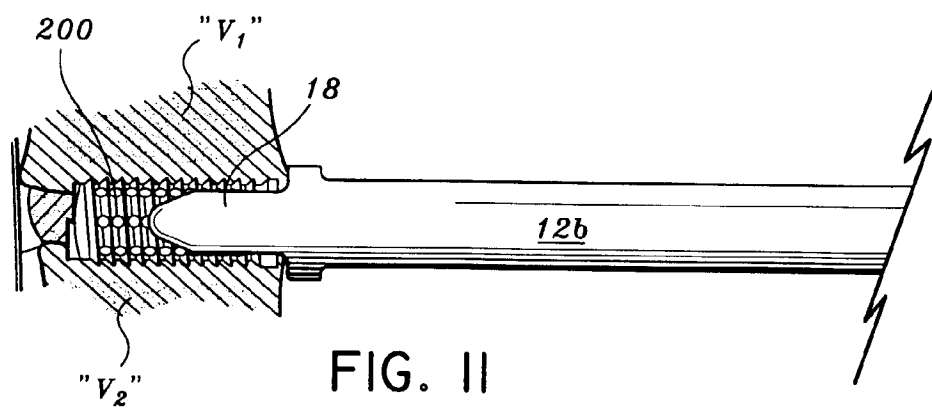
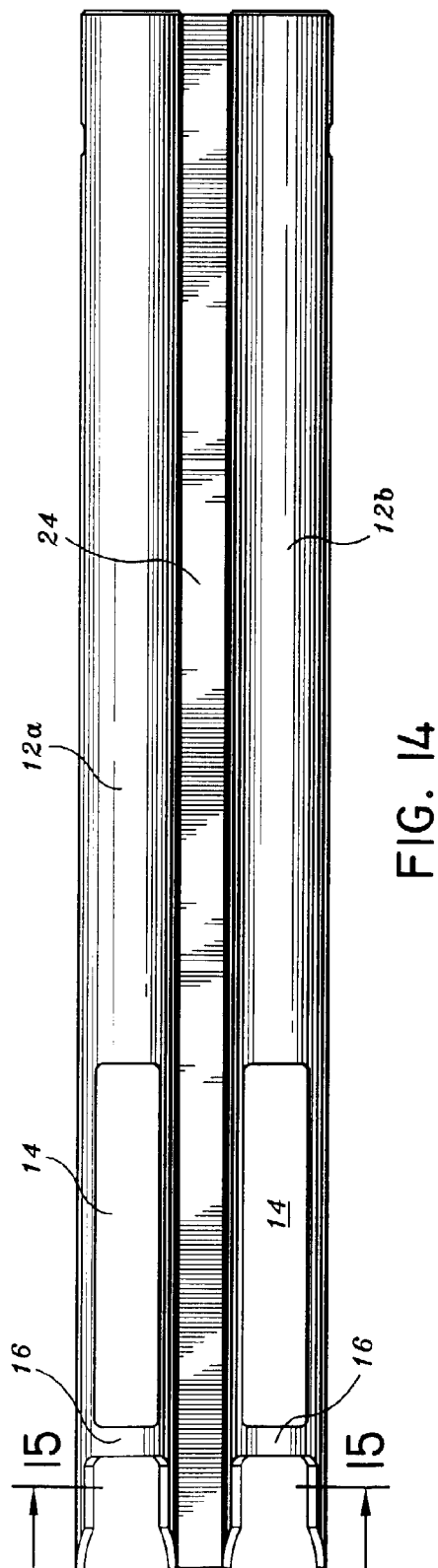
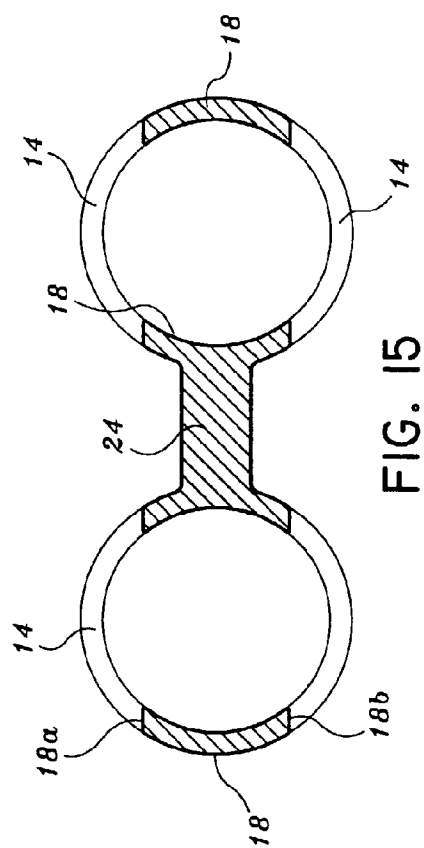
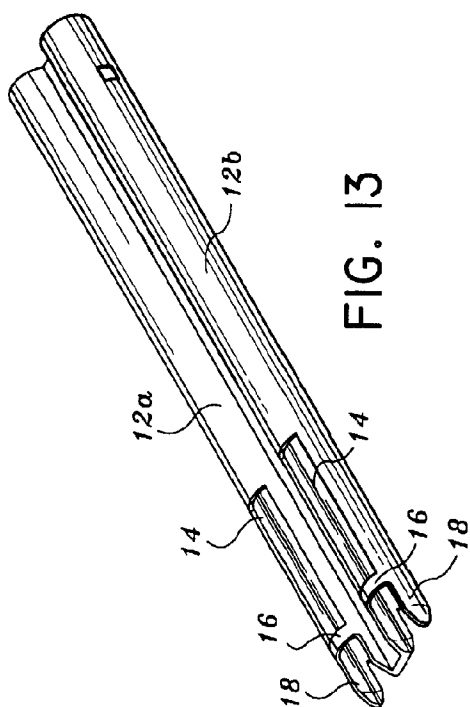


FIG. 9A







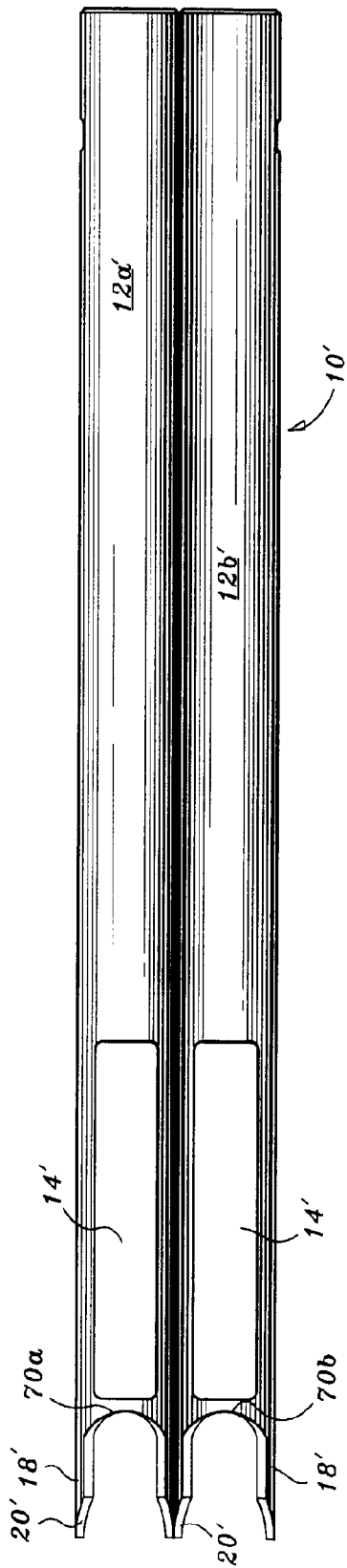
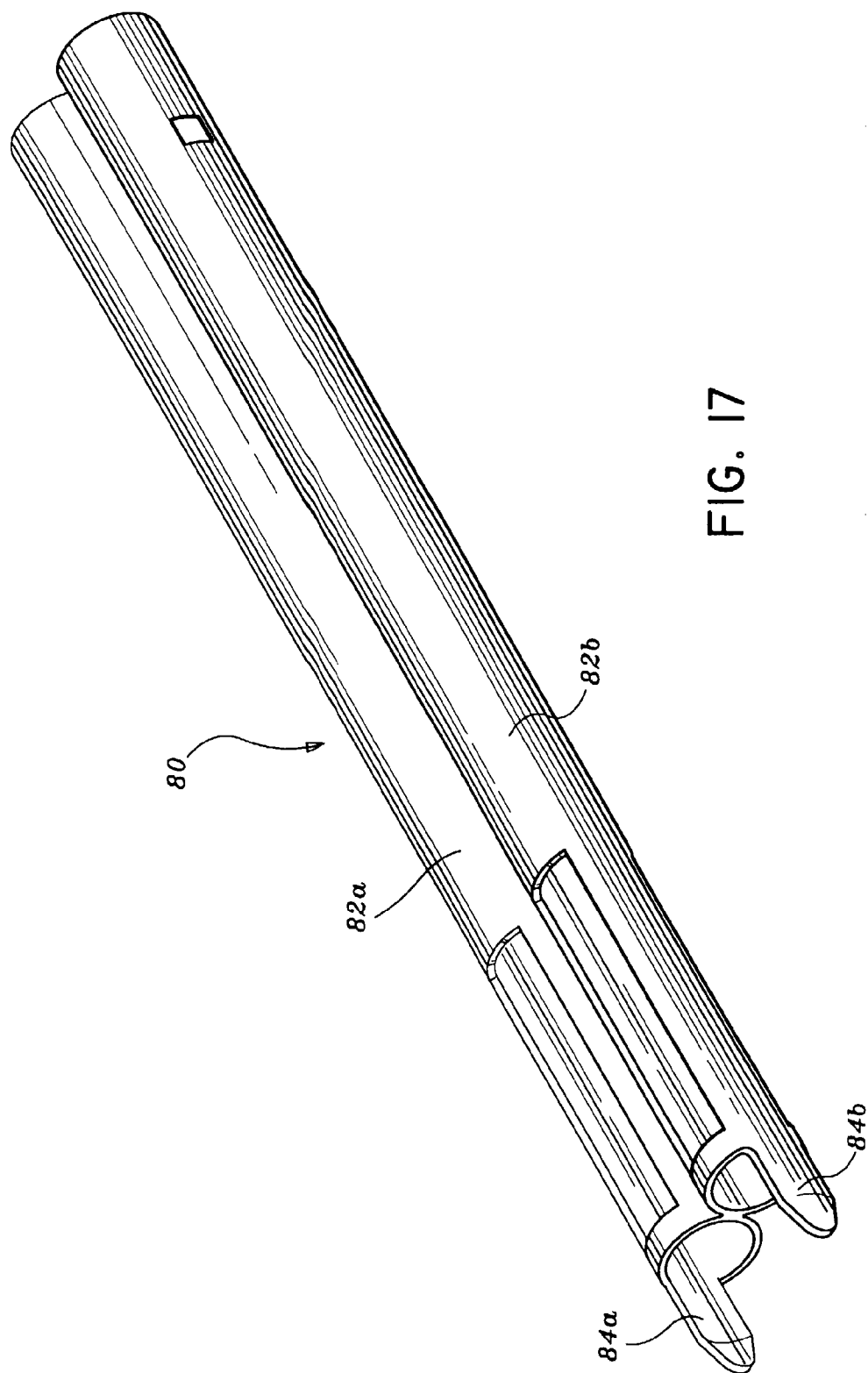


FIG. 16



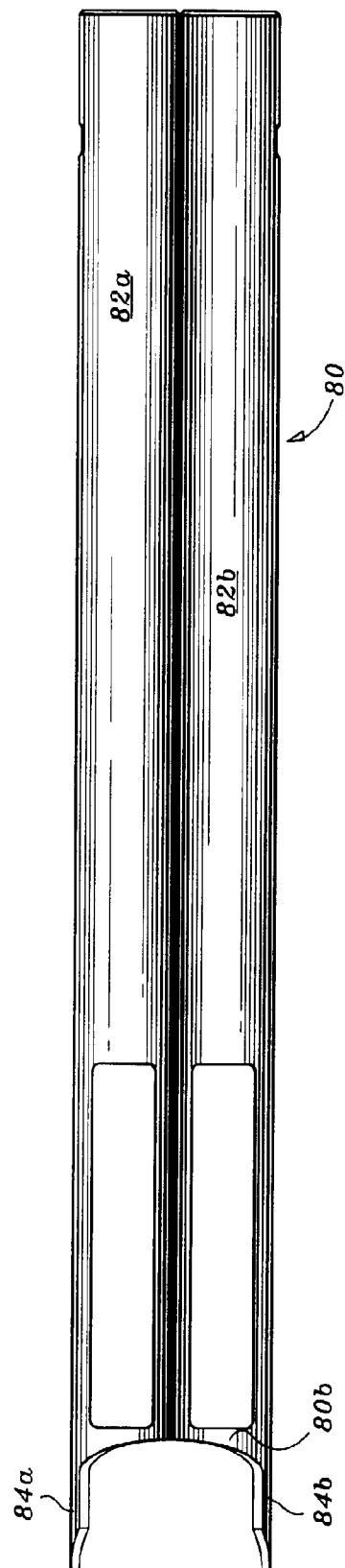


FIG. 18



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

EP 98 10 9238

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	WO 96 27345 A (MICHELSON) 12 September 1996 * page 88, last paragraph - page 91, paragraph 2; figures 25-27,33-35 *	1-18	A61B17/02 A61F2/46
X	US 5 571 109 A (BERTAGNOLI) 5 November 1996 * column 7, line 55 - column 8, line 25; figure 1 *	1-4,7,8	
A		16	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61B A61F
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 4 September 1998	Examiner Barton, S
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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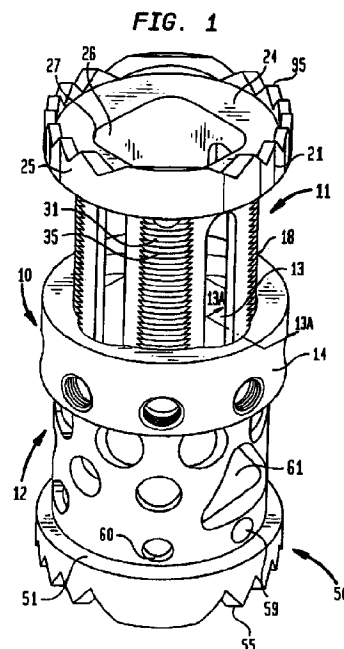
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(54) **Spinal implant**

(57) A corpectomy device has an inner member telescopically disposed in an outer member so that the inner member is movable in an axial direction. The inner and outer members are hollow, defining a chamber, and include apertures in communication with the chamber. A locking clip engages the inner and outer members to fix the position of the inner member with respect to the outer member. The longitudinal dimension of the device is adjustable by distracting the inner member so that the inner member extends from the outer member and moving the locking clip from an unlocked position to a locked position.



Description

FIELD OF THE INVENTION

[0001] The present invention relates to devices used to support the spine after removal of at least a part of a vertebra.

BACKGROUND OF THE INVENTION

[0002] When a vertebra becomes damaged or diseased, surgery may be used to replace the vertebra or a portion thereof with a prosthetic device for maintaining the normal spacing of the vertebrae and to support the spine. The prosthesis, which may be referred to as a corpectomy device, is inserted into the cavity created when the vertebra was removed. One such device disclosed by *Saggar*, U.S. Patent No. 5,702,455 includes a pair of cylindrical hollow members which are internally threaded and interact with a central cylindrical jacking screw which is externally threaded. The top part of the jacking screw is threaded in an opposite direction from a bottom part of the jacking screw. The jacking screw may be engaged and turned to adjust the vertical dimension of the device. When the jacking screw is turned, the hollow cylinders move either toward each other or away from each other.

[0003] Another prosthesis disclosed by U.S. Patent No. 5,290,312 to *Kojimoto et al.* has two hollow rectangular cylinders. Each cylindrical part has at least one open end. The tubular parts are sized and shaped so that one part is telescopically received in the other. The position of the parts in relation to each other are fixed by one or more set screws passed through apertures in one part to engage the other part. A corpectomy prosthesis disclosed by International Publication No. WO 92/01428 of *Rasheed* includes two parts, each having toothed surfaces. The position of the parts are fixed in relation to each other by the interengagement of the toothed surfaces.

[0004] Prostheses for supporting the spine after removal of a vertebra or a portion of a vertebra are desirably adjustable according to the size of the cavity created by the corpectomy procedure. The size of the cavity will depend upon the size of the particular patient, and the location of the cavity along the spine. In addition, the device may be adjusted either prior to insertion into the cavity or in situ within the cavity. For devices adjusted in situ, a convenient means for locking the device in the correct height is desirable. Although the patents discussed above present various solutions, further improvement in this area would be desirable.

SUMMARY OF THE INVENTION

[0005] The present invention addresses these needs.

[0006] One aspect of the present invention provides

a corpectomy device comprising a first member having a longitudinal axis, a second member moveable in an axial direction with respect to the first member, and a locking clip engagable with the first member and the second member and moveable between a first position and a second position for locking the first member and second member in a relative axial position with respect to one another. The corpectomy device has a locking clip so that the device may be positioned within the cavity created during the corpectomy procedure. distracted in situ, and locked in place. The device is adjustable to engage adjacent vertebrae while the locking clip is in an unlocked position. After adjustment, the locking clip may be moved to the locked position so that the device supports the spine.

[0007] In certain preferred embodiments, the second member includes at least one ridge and the locking clip includes at least one depression for locking the device. The at least one ridge is engaged in the at least one depression so that the locking clip engages the second member. In preferred embodiments, the locking clip and the second member include interengaging threads.

[0008] The locking clip may be mounted on the device in a number of ways. The locking clip may be rotatably movable between locked and unlocked positions, or otherwise movably mounted on the first member. The locking clip may be translatably moveable between locked and unlocked positions. The locking clip preferably includes a first bore and the first member preferably includes a corresponding hole. The first bore and the hole are engagable by a member, such as a set screw, for locking the position of the locking clip in its locked position.

[0009] The second member may be telescopically received in the first member. It is preferable that at least one of the first member and second member comprises a hollow member, the first member and the second member defining a chamber therebetween. It is also preferable that at least one of the first member and second member include perforations for permitting the ingrowth of bone, blood vessels, and other tissue. These perforations preferably include elongated perforations extending in the axial direction on one of the first member and the second member and substantially circular perforations on the other of the first member and the second member. At least one aperture is desirable for providing access to the chamber so that the device may be packed with fragments of bone, bone growth factors, or other material encouraging the growth of bone, blood vessels and other tissue, after being mounted within a patient. This aperture may also be used to fill the chamber with bone cement or other materials used in the procedure. Other perforations may be provided in sizes and shapes for encouraging ingrowth of tissue.

[0010] The corpectomy device preferably includes outwardly extending flanges on outer axial ends of the second member and the first member. The flanges pref-

erably include teeth so that the adjacent vertebrae may be engaged by the teeth, securing the device in the spine. The flanges are disposed at an acute angle, in certain preferred embodiments, with respect to the common longitudinal axis of the first member and the second member. The angled flanges adapt to differences in the curvature of different sections of the spine. The particular angles generally will depend upon the position of the device within the spine.

[0011] The second member may comprise an inner tubular member and the first member may comprise an outer tubular member having a passage extending therethrough. The passage may be polygonal in shape and centrally located in the outer tubular member. The passage engages the inner tubular member so that the inner tubular member is telescopically received in the outer tubular member.

[0012] The locking clip may engage the outer tubular member via a wedge on the locking clip. The outer tubular member may include a hole and the wedge on the locking clip would be engagable in the hole so that the locking clip engages the outer tubular member. To engage the inner tubular member and lock the device, the wedge may include a depression and the inner tubular member may include at least one bridge portion to be engaged in the depression.

[0013] The tubular cross-sectional shapes of the outer tubular member, inner tubular member and locking clip include various shapes. The passage of the outer tubular member has a cross-sectional shape which at least partially corresponds to the cross-sectional shape of the inner tubular member so that the inner tubular member is telescopically received in the passage. The tubular members may have an exterior surface defining a different shape than an exterior surface of the tubular members. The cross-sectional shape of the inner tubular member and the passage may be, for example, substantially square. However, the cross-sectional shape of the inner tubular member and the passage may also be triangular, that of a parallelepiped, elliptical, circular or other geometrical shapes. Non-circular shapes are preferred to prevent the inner tubular member from rotating with respect to the outer tubular member. The outer tubular member may include a wall having an inner surface defining the passage. The outer tubular member may also include an outer surface defining a cross-sectional shape different from the cross-sectional shape of the inner tubular member and the passage. The outer surface, for example, may define a cross-sectional shape of a square, triangle, parallelepiped, ellipse, circle, or other shapes.

[0014] Interrupted threads, grooves or ridges in mating surfaces of the locking clip and the inner tubular member may be used to lock the relative position of the inner and outer tubular member. The inner tubular member has an outer surface which may include first surface portions and second surface portions. An inner surface of the locking clip defines an aperture and may

include third surface portions and fourth surface portions. The third surface portions are shaped to correspond to the first surface portions on the inner tubular member so that the inner tubular member is telescopically received in the passage when the locking clip is in its unlocked position. The third and fourth surface portions are preferably curvilinear in shape and have different radii of curvature. The outer surface of the inner tubular member may define a substantially square cross-sectional shape, including rounded corners comprising the first surface portions and sides comprising the second surface portions. The inner surface of the locking clip includes circular surface portions comprising the fourth surface portions and rounded corners comprising the third surface portions. The rounded corners on the inner tubular member and the locking clip are in alignment when the locking clip is in its unlocked position. The circular surface portions may have ridges for engaging ridges on the rounded corners of the inner tubular member when the locking clip is in its locked position. In preferred embodiments, the circular surface portions on the locking clip and rounded corners of the inner tubular member have interengaging threads.

[0015] The corpectomy device may also comprise an inner member having a polygonal shape including corners, an outer member having a polygonal passage sized and shaped so that the inner member is telescopically and non-rotatably received in the outer member so that inner member and the outer member have a longitudinal axis. The device also has a removable locking clip having an inner surface defining an aperture including corners and locking portions. The locking clip is rotatably mounted on the outer member so that locking clip is limited in axial movement on the outer member. Mating surfaces on the locking portions and the corners on the inner member engage each other to prevent axial movement between the locking clip and the inner member.

[0016] The mating surfaces comprise, in preferred embodiments, threads on the locking portions of the locking clip and the corners of the inner member. The outer member may include a slot and the locking clip may include a pin mounted on the locking clip and extending through the slot to limit the axial movement of the locking clip. The pin may also be mounted so as to limit the rotational movement of the locking clip so that the clip is not rotated from an unlocked position, to a locked position, and then to a further unlocked position.

[0017] The outer member may include a hole and the locking clip may include a corresponding hole so that the holes may be engaged with a set screw for fixing the relative position of the locking clip with respect to the outer member. The inner member and outer member preferably each include a radially extending flange on an outer axial end of the inner member and the outer member. Most preferably, the flanges include teeth for engaging bone, especially the vertebrae adjacent the cavity formed during the corpectomy procedure. The

flanges are, in some preferred embodiments, disposed at an acute angle with respect to the longitudinal axis of the device to restore the curvature of the spine after the corpectomy device is installed.

[0018] Another aspect of the invention provides a method of providing support to the spine of a patient after a cavity is created in the spine by removing at least a portion of a vertebra or vertebrae, comprising inserting into the cavity an adjustable corpectomy device including an outer member having a longitudinal axis, an inner member movable in an axial direction with respect to the outer member, and a locking clip for locking the relative position of the inner and outer members with respect to one another. The method includes distracting the corpectomy device by moving the inner and outer members with respect to each other to increase the longitudinal dimension of the device to an appropriate size for supporting the spine, and moving the locking clip to a locked position to fix the relative position of the inner and outer members with respect to each other. The method also comprises packing a hollow chamber in the corpectomy device with materials for the encouraging the ingrowth of bone, blood vessels, and other tissue. The step of distracting may include inserting a first end and a second end of a distraction device into corresponding holes in the inner and outer members, and moving the first and second ends to move the inner and outer members in an axial direction away from each other.

[0019] The step of moving the locking clip preferably includes engaging the locking clip with the inner member. The step of moving the locking clip may include rotating the locking clip or snapping the locking clip into engagement with an inner member. The method may also include inserting a set screw into a hole in the locking clip and twisting the set screw until the set screw engages another hole in the outer member, at least one of the holes being threaded to receive the set screw.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] These and other features, aspects and advantages of the present invention will become better understood with regard to the following description, appended claims and accompanying drawings where:

Fig. 1 is a perspective view of a corpectomy device in accordance with an embodiment of the invention;
 Fig. 2 is a front elevational view of an inner member of the corpectomy device of Fig. 1;
 Fig. 2A is a rear elevational view of an inner member of the corpectomy device of Figs. 1-2;
 Fig. 3 is a cross-sectional view taken along line 3-3 in Fig. 2;
 Fig. 3A is a cross-sectional view taken along line 3A-3A in Fig. 3;
 Fig. 4 is an inverted, partial detail of the flange of

the inner cylinder of the corpectomy device of Figs. 1-3A;

Fig. 5 is a top view of the inner member of the corpectomy device shown in Figs. 1-4;

Fig. 6 is a right side elevational view of the outer member of the embodiment of Figs. 1-5;

Fig. 6A is a front elevational view of the outer member of the corpectomy device of Figs. 1-6;

Fig. 7 is a cross-sectional view taken along line 7-7 in Fig. 6;

Fig. 8 is a top view of a locking clip of the corpectomy device of Figs. 1-7;

Fig. 9 is a cross-sectional view taken along line 9-9 in Fig. 8;

Fig. 10 is a cross-sectional view taken along line 10-10 in Fig. 9;

Fig. 11 is a perspective view of the locking clip of the corpectomy device of Figs. 1-10;

Fig. 12 is a top view of the locking clip and outer member of the corpectomy device of Figs. 1-11 showing the locking clip in a position which allows movement of the inner member (not shown) to slide;

Fig. 13 is a top view of the locking clip and outer cylinder of the corpectomy device of Figs. 1-12, showing the locking clip in a position in which the inner member is prevented from axial movement with respect to the outer member;

Fig. 13A is a partial cross-sectional view taken along line 13A-13A in Fig. 1;

Fig. 14 is a schematic, perspective view of a corpectomy device in accordance with the embodiments of Figs. 1-13A and a distractor for installing the corpectomy device;

Fig. 15 is a perspective view of a corpectomy device in accordance with another embodiment of the invention;

Fig. 16 is a front elevational view of an outer cylinder of the embodiment of Fig. 15; and

Fig. 17 is a perspective view of a locking clip in accordance with the embodiment of Figs. 15-16.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0021] Referring to Fig. 1, there is shown a corpectomy device 10 comprising an inner member 11 which may be cylindrical in shape or may have any polygonal cross-section, telescopingly received in an outer member 12 which may also be a cylinder. The device further includes a locking clip 14 having a locked position and an unlocked position, the locking clip being engagable with the inner member and the outer member for locking the inner member and the outer member in a relative position with respect to one another in a manner described in detail below.

[0022] Referring to Figs. 1-3A, the inner member 11 has a top end 15 and a bottom end 16 and is essentially

comprised of a wall 17 extending between ends 15 and 16 and defining a hollow tubular part 18 having an inner surface 19 and an outer surface 20. In the preferred embodiment, a top end 15 is generally circular and the cross-section of part 18 is generally square with outer rounded corners 31. Top end 15 has a circular base 24 and also includes an aperture 26 in the center of circular base 24. Aperture 26 is generally square in shape, and has rounded corners 27. Inner surface 19 of wall 17 defines a hollow space 30. Hollow space 30 extends from bottom end 16 of inner member 11 to aperture 26 in circular base 24. The inner hollow space is essentially square having rounded corners 37 defined by rounded corners 31 of wall 17.

[0023] The outer surface 20 of wall 17 defines different surface portions. In the preferred embodiment, the outer surface 20 includes first surface portions having rounded corners 31 and second surface portions 32' comprising sides 32 of the generally square cross-section. Rounded corners 31 of wall 17 have ridges 35 on outer surface 20. Sides 32 join adjacent rounded corners 31 of the wall 17. In the preferred embodiment, and as best seen in Fig. 2, sides 32 have orifices 33 which are elongated and extend in an axial direction in wall 17 of inner member 11. Orifices 33 communicate with hollow space 30.

[0024] Top 15 is preferably in the form of a flange 21 connected to or integral with tubular part 18, so that tubular part 18 extends from the bottom end 16 to the underside of flange 21. As best seen in Fig. 3A, flange 21 includes circular base 24 and preferably includes a peripheral extension, or wall 25, extending outwardly from circular base 24 with teeth 28 for engaging vertebrae adjacent a cavity within the spine.

[0025] Holes are provided in the inner cylinder adjacent the flange 21. At least one hole 38 is provided in a side 32 of wall 17 and at least one other hole 39 is provided in at least one corner 31 of wall 17. These holes are preferably provided so that they may be engaged by an instrument for distracting corpectomy device 10, as will be further explained below.

[0026] The dimensions of an inner member for a corpectomy device in accordance with the invention may be as follows, although the dimensions of the embodiment shown in the figures are not critical to the invention.

[0027] As best seen in Fig. 3A, wall 25 has a height y of about 6 mm and circular base 24 has a thickness t of about 2 mm. Each of teeth 28, as best seen in Fig. 4, is comprised of two adjacent surfaces extending in a direction away from base 24. Surfaces 29, 34 are disposed at an angle with respect to each other. The surfaces 29 and 34 define an angle α , which is preferably 90°. Each tooth has an apex 48 and the distance between adjacent apexes is about 4 mm. The extension 25 and teeth 28 form an angled toothed surface which, in the embodiment shown, is angled from the horizontal by 4°. This angle preferably varies, depending upon the

application, as discussed below.

[0028] In the preferred embodiment, and as seen in Figs. 2 and 3, the tubular part 18 of inner member 11 has a height H of about 36 mm. The preferred square tubular part has an exterior width W of about 22 mm, measured across the tube from outer surface 20 at one side 32 thereof to outer surface 20 of an opposite side 32. An inner width X is about 17 mm, measured from the inner surface 19 of one side 32 to inner surface 19 of an opposite side 32. This dimension of course may vary with the wall thickness. Rounded corners 31 on the substantially square part 18 are defined by a circle having diameter of 4 millimeters. The ridges 35 are formed by recesses in rounded corners 31 and preferably comprise a left-handed thread such as a metric M26 x 1 thread. A person of ordinary skill may easily convert this designation to a thread based upon the U.S. system of dimensions.

[0029] Orifices or slots 33 in sides 32 of the part 18 have a height l_1 of about 30 mm and are spaced from the base of flange 21 a distance of about 2.5 mm (distance d shown on Fig. 2A). The orifice 33 adjacent hole 38 has a height l_2 of about 27 mm to accommodate hole 38 located underneath the base of flange 21, as shown in Fig. 2.

[0030] Referring to Figs. 1 and 6-7 there is shown outer member 12 having an upper end 40 and a lower end 41. The outer member 12 includes a wall 42 having an outer surface 43 and an inner surface 44. In the preferred embodiment, an outer surface 43 defines a circular cross-section for the outer member 12, while inner surface 44 defines a substantially square cross-sectional shape for passage 45, extending from the upper end 40 to the lower end 41 and sized to receive part 18 of inner member 11. Passage 45 may be centrally located within the outer member and has rounded corners 46 defined by the inner surface 44 of wall 42. Passage 45 also has sides 47 also defined by the inner surface of wall 42 and extending between the rounded corners 46. The rounded corners 46 are shaped to correspond to rounded corners 31 of inner member 11, while the sides 47 are shaped to correspond to sides 32 of inner member 11 so that inner member 11 is telescopically received in passage 45 of outer member 12.

[0031] A flange 50 is disposed at lower end 41 of outer member 12. The flange 50 is constructed similarly to the flange 21 of member 11. In the preferred embodiment, both flange 21 and flange 50 have a diameter D of about 34 mm. Like top flange 21, flange 50 has a circular base 51 and an inner aperture 52 with corners 53. Flange 50 also preferably includes an outwardly extending peripheral wall 54 with teeth 55 in an outer surface of wall 54 for engaging the vertebrae adjacent flange 50. Apertures 26 and 52 allow ingrowth of bone, blood vessels and other tissue from the vertebrae adjacent to flange 21 and flange 50. The peripheral wall 54 and teeth 55 also form an angled toothed surface having the same or different angle from that of flange 21.

[0032] Outer member 12 has orifices 58, defined by wall 42, as seen in Figs. 1, 6, 6A, and 7. Orifices 58 extend from outer surface 43 to inner surface 44, communicating with passage 45. The orifices 58 allow the ingrowth of bone, blood vessels, and other tissue into the corpectomy device after the corpectomy device 10 is installed in a patient. The outer member 12 also includes holes 59 and 60, which correspond with holes 38 and 39 on inner member 11, for distracting the corpectomy device 10. Holes 59 and 60 extend through wall 42 and are located adjacent lower flange 50. Outer member 12 also preferably includes an aperture 61 which is located in wall 42 to provide access to passage 45 from the exterior of the corpectomy device 10. Through aperture 61, passage 45 may be packed with bone cement, which may be used to fix the device, although bone cement is not required. Aperture 61 may also be used to pack into the device chips of bone, materials for fixing the corpectomy device in the patient's body, or materials promoting the growth of bone, blood vessels, and other tissue. In the preferred embodiment, aperture 61 has a height f of about 12 mm. Preferably, a slit 62 in wall 42 of the outer member 12 extends from the outer surface 43 to the inner surface 44 and is elongated in a circumferential direction for moveably mounting the locking clip on the outer cylinder. Slit 62 has a first side 78 and a second side 76, both formed by wall 42. The preferred slit 62 has a height e of about 2 mm and a central horizontal plane 75 which is spaced about 6 mm from upper end 40. The preferred circumferential angle, ϕ , between first side 78 and second side 76 is 53° .

[0033] The preferred outer member 12 has a height k of about 35 mm measured from the upper end 40 to flange 50. Flange 50 has dimensions which are the same as flange 21. Generally square passage 45 has a width m of about 22 mm, measured from the inner surface 44 of a side 47 to the inner surface of an opposite side 47. Rounded corners 46 are defined by the same radius as rounded corners 31 on inner member 11. Outer surface 43 defines a circular cross-sectional shape having a preferred diameter B of about 30 mm.

[0034] As best seen in Figs. 6 and 6A, the preferred embodiments include orifices 58 which are preferably arranged in rows around the circumference of member 12 in horizontal planes. The holes 58 in each succeeding row may be staggered in relation to each other. The first row 70 of orifices 58 may be located in wall 42 so that their plane 74 is spaced about 6 mm from upper end 40. Seven holes are equally spaced around wall 42 in row 70, each having a diameter of about 6 mm. Second row 71 has orifices 58 with their plane 74 spaced 14 mm from upper end 40. Eight holes are equally spaced along wall 42 in row 71, each having a diameter of about 7 mm. Row 70 has one fewer holes than row 71, to accommodate the horizontal slit 62 in row 70. The third row 72 has orifices 58 arranged so that the plane 74 is about 22 mm from the upper end 40. Seven holes are

arranged in the third row 72, each having a diameter of about 6 mm. Fourth row 73 has orifices 58 arranged so that their plane 74 is spaced about 30 mm from upper end 40. This row has five holes, each having a diameter of about 6 mm. The fourth row 73 only has five holes and third row 72 only has seven rows to accommodate aperture 61. Aperture 61 is substantially triangular in shape, having rounded corners 63 and sides 64. The aperture 61 provides access to chamber 95 so that the device may be packed with bone fragments, bone growth factors, other materials promoting the growth of bone, blood vessels or other tissue, or materials used in the corpectomy procedure. Adjacent sides 64 of aperture 61 define an angle β of 70° .

[0035] The preferred locking clip, as best seen in Figs. 8-10, has a top side 80 and a bottom side 81. The top side 80 of the locking clip 14 comprises a circular disk 82 having an inner surface 87 defining an aperture 83 including surfaces having threads. Extending downwardly from the periphery of circular disk 82 is a wall 84, defining an open side or bore 85 at the bottom side 81 of the locking clip. The locking clip is mounted on surface 40 of outer member 12, as will be described below.

[0036] The inner surface includes third surface portions 89' shaped to correspond to the first surface portions 31 on the inner member so that the inner member is telescopically received in the passage 45 when the locking clip is in its unlocked position shown in Figure 13. The inner surface 87 also includes fourth surface portions 88'.

[0037] In the preferred embodiment, aperture 83 has the shape of the rounded square cross-sectional shape of passage 45 intersected with a circle 86. The aperture 83 is defined by surface portions 89' comprising rounded corners and surface portions 88' comprising threaded circular surface segment portions 88 of circle 86. The rounded corners 89 are shaped to correspond to rounded corners 46 of outer member 12 and corners 31 of member 11. Referring to Fig. 11, circular surface portions 88 have threads or ridges 90 extending along surface 87. The threads 90 on circular surface portions 88 engage threads on corner 31 to enable the locking clip to lock the inner member 11 in a position with respect to outer member 12. To accomplish this, locking clip 14 has a locked position and an unlocked position with respect to inner member 11 and outer member 12. Fig. 13 depicts the position of the locking clip with respect to the outer member 12 when locking clip 14 is in its locked position on inner member 18. Fig. 12 depicts the position of the locking clip with respect to member 12 when it is in its unlocked position, thus allowing inner member 18 to slide freely.

[0038] Locking clip 14 has a set of bores 91 arranged around the circumference thereof on a common horizontal plane 92. There are eight bores 91 equally spaced along wall 84 of locking clip 14. Each bore 91 has a corresponding orifice 58 in first row 70 on outer member 12. The bores 91 and orifices 58 in first

row 70 may be used to further lock the device, as discussed below. Locking clip 14 may also have an orifice 93 for permanently mounting the locking clip 14 on the outer member 12. A pin 96, which is shown in Fig. 10, is mounted in orifice 93 and extends past interior surface 94 of wall 84 and inwardly into slit 62 on outer member 12. The pin 96 rotatably mounts locking clip 14 on the outer member 12 allowing rotation thereon but preventing axial movement. During manufacture, the pin may be welded into place on the locking clip so that the locking clip is pre-mounted on the outer member.

[0039] The preferred locking clip 14 has a diameter g of about 34 mm. The open side or bore 85 of locking clip 14 has a diameter h of about 30 mm. The thickness of wall 84 may be about one or two millimeters. The height i from the top side 80 to the bottom side 81 of the locking clip is about 13 mm. The thickness j of the circular disk 82 is about 3 mm. In the preferred embodiment, the circular surface positions 88 of aperture 83 in disk 82 has 26 mm, or M26 x 1, left-handed threads corresponding to the threads on member 11. Rounded corners 89 have a radius of about 6 millimeters, the radius being measured from a point 5.6 millimeters from an axis 200 and 6.5 millimeters from an axis 201 in Fig. 8. Bores 91 are arranged on plane 92 so that the plane is spaced 9 mm from top side 80. Preferably, bores 91 have a diameter of about 6 mm and are threaded to receive screws. Orifice 93 has a diameter of about 2 mm.

[0040] The locking clip 14 is mounted on the outer member 12 by placing the locking clip 14 on the outer member 12 so that the upper end 40 of the outer cylinder is received in the open side or bore 85 of the locking clip. A pin is then mounted in orifice 93 or attached to the inner surface 94 of the locking clip so that the pin extends into slit 62. Locking clip 14 is mounted on the outer member 12 and is rotatable thereon so that locking clip 14 has a locked position and an unlocked position. Figs. 12 and 13 illustrate a top view of the locking clip mounted on the outer member. In Fig. 12, the assembly is shown so that the locking clip 14 is its unlocked position. In this position, the pin in slit 62 is adjacent side 78 or side 76 of slot 62. Whether side 76 or 78 is the unlocked position is a matter of design choice. Inner member 11 may then be inserted into passage 45 so that bottom end 16 is received in the passage. When the locking clip 14 is in the unlocked position, rounded corners 89 of the locking clip are aligned with rounded corners 46 of the outer member 12. Circular surface portions 88, which have ridges or threads 90, are then aligned with sides 47 of the outer member 12. When the locking clip is in a locked position, the pin in slit 62 is adjacent the other of sides 78 and 76. As shown in Fig. 13, rounded corners 89 are aligned with sides 47 when the locking clip is in the locked position.

[0041] To assemble the device, the bottom end 16 of inner member 11 is inserted through aperture 83 and

into the passage 45 of outer member 12. When the inner member has been inserted into passage 45, passage 45 and hollow space 30 form a chamber 95. In order to insert the inner member into passage 45, rounded corners 46 on the outer member must be aligned with rounded corners 89 on the locking clip 14 so that locking clip 14 is its unlocked position. When the locking clip is moved to its locked position, circular surface portions 88 having threads or ridges 90, overlap rounded corners 46 and engage the ridges or threads 35 on the rounded corners 31 of inner member 11. Fig. 13A illustrates the engaging threads of clip 14 and member 11. In this position, the relative position of the inner member 11 is axially fixed with respect to the outer member 12. The position of the locking clip 14 is fixed in this locked position by inserting one or more screws into bores 91 so that the screws extend into orifices 58 in first row 70 on the outer member 12. If the locking clip is not pre-mounted on the outer member prior to insertion of member 11, the locking clip 14 will be placed on end 40 of the outer member 12 and pin 96 may be mounted in hole 93 of the locking clip, extending into slot 62.

[0042] The length of slit 62 is approximately equal to the horizontal dimension of the rounded corners 31. These dimensions are desirable so that the locking clip is prevented from rotating beyond its locked position and the ridges or threads 90 and 35 are prevented from coming out of engagement with each other by rotating the locking clip too far beyond its locked position. Thus, when the locking clip is in its locked position, the pin 96 mounted on the locking clip is abutted against one of the first side 78 or second side 76. Likewise, when the locking clip is moved into its unlocked position so that rounded corners 31 are aligned with rounded corners 89, the pin 96 mounted to the locking clip 14 is abutted against the other of the first side 78 or second side 76.

[0043] To use the corpectomy device, the locking clip is mounted on outer member 12 and is initially in its unlocked position and the inner member is assembled with the outer member and locking clip. The passage 45 is filled by the surgeon with bone material, bone growth factors, bone morphogenic proteins (BMP's), or other materials for encouraging bone growth or growth of other tissue through the many apertures provided in the device. The device is distracted by inserting one end 98 of a distractor or distraction device 97 into holes 38 and/or 39 and the other end 99 of the distractor into holes 59 and/or 60 and separating the ends of the distractor so that the inner member 11 is drawn upwardly and away from the outer member 12 to the desired overall height. The locking clip 14 is then rotated to the locked position and one or more set screws are inserted into the bores 91 to fix the position of the locking clip with respect to the outer member. The one or more set screws prevent the locking clip 14 from rotating. Thus, the corpectomy device may be distracted in situ and conveniently locked in position so that the device may be adjusted to the height required to replace a removed

vertebra and support the spine. Bone cement is not required to lock the device, but may be used. Preferably, the device is tapped with a hammer so that the teeth on top flange 21 and lower flange 50 engage the adjacent vertebrae.

[0044] The inner member 11, outer member 12, locking clip 14 and any set screws are preferably comprised of titanium but may also be comprised of stainless steel, ceramics, composite materials, other materials known in the surgical and medical arts, and/or biologically inert materials may be used. The orifices 58, aperture 61, apertures 26 and 52, and orifices 33 may have any shape. Curvilinear shapes are preferred, however, for ease of manufacture. The device must also support the patient's spine and corners create increased regions of stress in the device. The elongated orifices 33 in inner member 11 are preferred so that after the device is distracted, the surgeon can pack additional bone material, or other material desired, into the device. In addition, the relatively large aperture 61 is convenient for packing the device with such materials.

[0045] The cross-sectional shapes of the part 18, hollow space 30, outer surface 43 of outer member 12, passage 45 and aperture 83 may have any shape which allows the inner member to be slidably received in passage 45 and allows locking clip 14 to engage the inner and outer members to lock the relative position of the inner member with respect to the outer member. For example, the part 18, passage 45 and aperture 83 may have shapes including a triangle, pentagon or octagon. It is also preferred that the inner member does not rotate with respect to the outer member 12. The locking clip and inner member may engage one another in a number of ways. For example, the engaging elements 90 and 35 discussed above may comprise ridges, threads or grooves formed on rounded corners 31 of part 18 and circular surface portions 88 of locking clip 14. Preferably, the threads, grooves, or ridges are disposed along a horizontal straight line, for ease of manufacture. If it is desirable that the position of the inner member 11 is adjusted either upwardly or downwardly as the locking clip 14 is moved to its locked position, the ridges 90 and 35 may comprise threads which are slightly angled in a vertical direction. Alternatively, circular surface portions 88 may have depressions and rounded corners 31 may have ridges which are engaged in the depressions.

[0046] The particular dimensions of the device discussed above are dimensions for that particular embodiment only. Use of the corpectomy device in the spines of different patients, and in different positions along the spine, will require variations in the dimensions. Thus, a variety of devices having different heights and diameters may address different applications and the preferences of different surgeons. The particular angle for the top and lower flanges will also vary according to the particular application and the surgeon's preference. The flanges may be angled anywhere from 0° to 8° or much

greater to restore the curvature of the spine. The particular dimensions are not critical to the invention. In one variation, the teeth 28 and 55 may be replaced by, or used in addition to, screws anchoring the device to adjacent vertebrae. Holes may be provided in the top flange and lower flange for insertion of the screws, which can engage adjacent vertebrae.

[0047] Another embodiment of the invention is illustrated in Figs. 15-17. In this embodiment, inner member 111 is slidably received in outer member 112, which have interengaging circular cross-sectional shapes and a common longitudinal axis 146. Inner member 111 preferably has a flange 121 at outer axial end of the member, the flange 121 has teeth for engaging an adjacent vertebra. The inner member includes a tubular part 118 extending from flange 121. The inner member 111 has a series of apertures or slots 151 defining circumferential bridges 152 therebetween. Orifices 133 similar to orifices 33 are provided in the part 118.

[0048] The outer member 112 has orifices 158. Orifices 158 and 133 may be the same or similar to the orifices described in reference to the preferred embodiment above. The outer member 112 has an upper end 140 and a lower end 141, a hole 143 extends through the outer member 112 to chamber 195 defined by inner and outer members. Notches 142 are formed in the outer cylinder 112, on either side of hole 143 for interaction with locking clip 114. Notches 142 have walls 147 in which holes 144 are formed, one in each notch for mounting the locking clip 114 on the outer member 112. The outer member 112 preferably includes an aperture 161, which may have the elongated shape shown in Figs. 15 and 16, or may have the shape of aperture 61 discussed above.

[0049] The locking clip 114 of this embodiment has the shape of a portion of a cylinder and is sized and shaped to be mounted on an outer surface of the outer member 112, which has a circular cross-section in this embodiment. Locking clip 114 has a curved wall 184 extending downwardly from a curved arm piece 182. The arm piece 182 has an inner surface 194 and a wedge portion 188 having a straight face 189 extends inwardly from the arm piece 182. The wall 184 has apertures 191 which correspond to a first row of orifices formed in the outer cylinder 112 similarly to the first row 70 of orifices 58 discussed above.

[0050] On the inner face 189 of the wedge portion 188, a depression 186 is formed having side walls 190 extending horizontally into wedge portion 188. Arm 182 has a first end 160 and second end 162 on either side of the wedge portion 188. The locking clip includes pins 163 on the inner surface 194 adjacent ends 160 and 162. The wedge portion 188 includes a top surface 153 and bottom surface 154. Depression 186 defines portions 155 and 156 in inner surface 189 on either side of depression 186.

[0051] The notches 142 on the outer cylinder 112 receive the ends 160 and 162 of arm 182. Locking clip

114 is mounted on outer cylinder 112 in notches 142 so that the pins 163 are received in the holes 144 on the outer cylinder. Holes 144 are elongated in a horizontal direction. Holes 144 each have a first side and a second side. When the locking clip 114 is mounted on outer cylinder 112, the depression 186 in the wedge portion 188 is disposed in aperture 143 in the outer cylinder but does not protrude into passageway 145. The depression 186 is open to the passage 145 in outer cylinder 112. The locking clip is preferably pre-mounted on the outer cylinder 112, but may be snapped into place when the device is installed.

[0052] Locking clip 114 has an unlocked position, in which pins 163 abut one side of the holes 144. The inner member 111 may be inserted into passageway 145 when the locking clip is in its unlocked position because wedge portion 188 does not protrude through aperture 143 into passageway 145. Locking clip 114 also has a locked position in which pins 163 abut the other sides of the holes 144. In this position, the wedge portion 188 protrudes into the aperture 143 and wedge portion 188 is located in passageway 145. After the inner cylinder 111 has been inserted into passageway 145, locking clip 114 may be translated into its locked position. The locking clip is moved into its locked position by translating the clip 114 in a direction transverse to the longitudinal axis 146. In its locked position, the depression 186 on the locking clip engages an bridge 152 on the inner cylinder. When the locking clip 114 is moved to its locked position, bridge 152 is received in depression 186, and portions 155 and 156 on the face 189 are received in holes 151 adjacent the particular bridge 152 engaged by depression 186 in the locking clip.

[0053] As will be readily appreciated, numerous other variations and combinations of the features discussed above will be employed without departing from the present invention. Accordingly, the foregoing description of certain preferred embodiments should be taken by way of illustration, rather than by way of limitation, of the features discussed above.

Claims

1. A corpectomy device, comprising:
 - a) a first member having a longitudinal axis;
 - b) a second member moveable in an axial direction with respect to said first member; and
 - c) a locking clip engagable with said first member and said second member and moveable between a first unlocked position and a second locked position for locking said first member and said second member in a relative axial position with respect to one another.
2. The corpectomy device of claim 1, wherein said locking clip includes at least one depression and said second member includes at least one ridge engagable in said at least one depression for locking said first member and said second member in a relative position with respect to one another.
3. The corpectomy device of claim 1, wherein said locking clip and said second member include inter-engaging threads for locking said first member and said second member in a relative axial position with respect to one another.
4. The corpectomy device of claim 3, wherein said locking clip is rotatably mounted on said first member for rotation into and out of engagement with said threads.
5. The corpectomy device of claim 1, wherein at least one of said first member and said second member comprises a hollow member, said first member and said second member defining a chamber therebetween.
6. The corpectomy device of claim 5, wherein said second member is slidably and telescopingly received in a passageway of said first member for movement in said axial direction.
7. The corpectomy device of claim 6, wherein said first member and said second member have a common, longitudinal axis and said locking clip is translatable movable to said locked position in a direction transverse to said axis.
8. The corpectomy device of claim 6, wherein said locking clip is movably mounted on said first member.
9. The corpectomy device of claim 8, wherein said locking clip includes a first bore and said first member includes a corresponding hole, said first bore and hole being engagable by a screw for locking the position of said locking clip in its locked position.
10. The corpectomy device of claim 6, wherein said first member and said second member include perforations for permitting ingrowth of bone, blood vessels and other tissue.
11. The corpectomy device of claim 10, wherein said perforations include:
 - a) elongated perforations extending in the axial direction on one of said first member and said second member; and
 - b) substantially circular perforations on the

other of said first member and said second member.

12. The corpectomy device of claim 6, wherein:

a) at least one of said first member and said second member include an aperture providing access to said chamber for packing said chamber with material encouraging the growth of bone, blood vessels and other tissue.

13. The corpectomy device of claim 6, wherein:

a) said second member and said first member have outer axial ends with outwardly extending flanges including teeth on a surface thereof for engaging bone.

14. The corpectomy device of claim 13, wherein said flanges are disposed at an acute angle with respect to a common longitudinal axis of said first member and said second member.

15. The corpectomy device of claim 6, wherein said second member comprises an inner tubular member and said first member comprises an outer tubular member having a passage for engaging said inner tubular member, said inner tubular member being telescopingly disposed within said outer tubular member.

16. The corpectomy device of claim 15, wherein said outer tubular member includes a hole and said locking clip includes a wedge shaped to be engaged in said hole so that said locking clip engages said outer tubular member.

17. The corpectomy device of claim 16, wherein said wedge includes a depression and said inner tubular member includes at least one bridge portion to be engaged in said depression so that said locking clip engages said inner cylinder.

18. The corpectomy device of claim 15, wherein said inner tubular member has an outer surface including first surface portions and second surface portions.

19. The corpectomy device of claim 18, wherein said locking clip has an inner surface defining an aperture, said inner surface including third surface portions and fourth surface portions, said third surface portions being shaped to correspond to said first surface portions so that said inner tubular member is telescopingly received in said passage when said locking clip is in its unlocked position.

20. The corpectomy device of claim 15, wherein said

locking clip has an inner surface including third surface portions and fourth surface portions, each being curvilinear and having different radii of curvature.

21. The corpectomy device of claim 19, wherein said outer surface of said inner tubular member defines a substantially square cross-sectional shape, including sides comprising said second surface portions and rounded corners comprising said first surface portions.

22. The corpectomy device of claim 21, wherein said inner surface on said locking clip includes circular surface portions comprising said fourth surface portions and rounded corners comprising said third surface portions so that said rounded corners on said locking clip are aligned with said rounded corners on said inner tubular member when said locking clip is in its unlocked position.

23. The corpectomy device of claim 22, wherein said circular surface portions on said locking clip and said rounded corners on said inner tubular member include ridges for locking said inner tubular member and said outer tubular member in a relative position with respect to one another when said locking clip is in its locked position.

24. The corpectomy device of claim 22, wherein said circular surface portions on said locking clip and said rounded corners on said inner tubular member include interengaging threads for locking said inner tubular member and said outer tubular member in a relative position with respect to one another.

25. The corpectomy device of claim 15, wherein said outer tubular member includes a wall having an inner surface defining said passage and an outer surface, said outer surface defining a cross-sectional shape different from said cross-sectional shape of said inner tubular member and said passage.

26. The corpectomy device of claim 15, wherein said outer tubular member includes a wall having an inner surface defining said passage and an outer surface, said outer surface defining a circular cross-sectional shape.

27. A corpectomy device, comprising:

a) an inner member having a polygonal shape including corners;

b) an outer member having a polygonal passage sized and shaped so that said inner member is telescopingly and non-rotatably received

in said outer member so that said inner member and said outer member have a longitudinal axis;

c) a movable locking clip having an inner surface defining an aperture including corners and locking portions, said locking clip being rotatably mounted on said outer member so that said locking clip is limited in axial movement on said outer member; and

d) mating surfaces on said locking portions and said corners of said inner member for interengagement to prevent axial movement between said locking clip and said inner member.

28. The corpectomy device of claim 27, wherein said mating surfaces comprise threads on said locking portions and said corners of said inner member.

29. The corpectomy device of claim 27, wherein said outer member includes a slot and said locking clip includes a pin mounted on said locking clip and extending through said slot for limiting the axial movement of said locking clip.

30. The corpectomy device of claim 29, wherein said pin extends through said slot to limit the rotational movement of said locking clip.

31. The corpectomy device of claim 27, wherein said outer member includes a hole and said locking clip includes a corresponding hole, said hole on said outer member and said hole on said locking clip being engageable with a set screw for fixing the relative position of said locking clip and said outer cylinder with respect to each other.

32. The corpectomy device of claim 27, wherein:

a) said inner member includes a radially extending first flange on an outer axial end of said inner member, said first flange including teeth on a surface of said first flange for engaging bone; and

b) said outer member includes a radially extending second flange on an outer axial end of said outer member, said second flange including teeth on a surface of said second flange for engaging bone.

33. The corpectomy device of claim 32, wherein said first flange and said second flange are disposed at an acute angle with respect to said longitudinal axis.

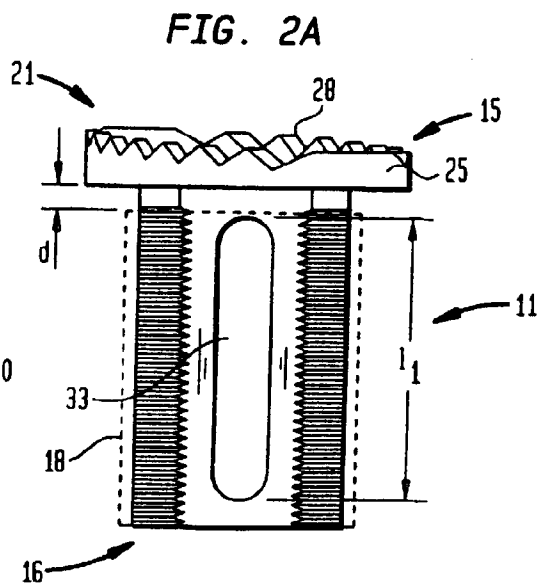
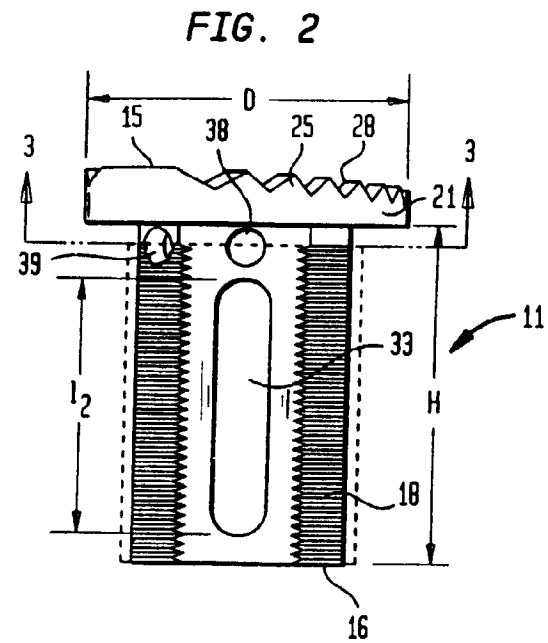
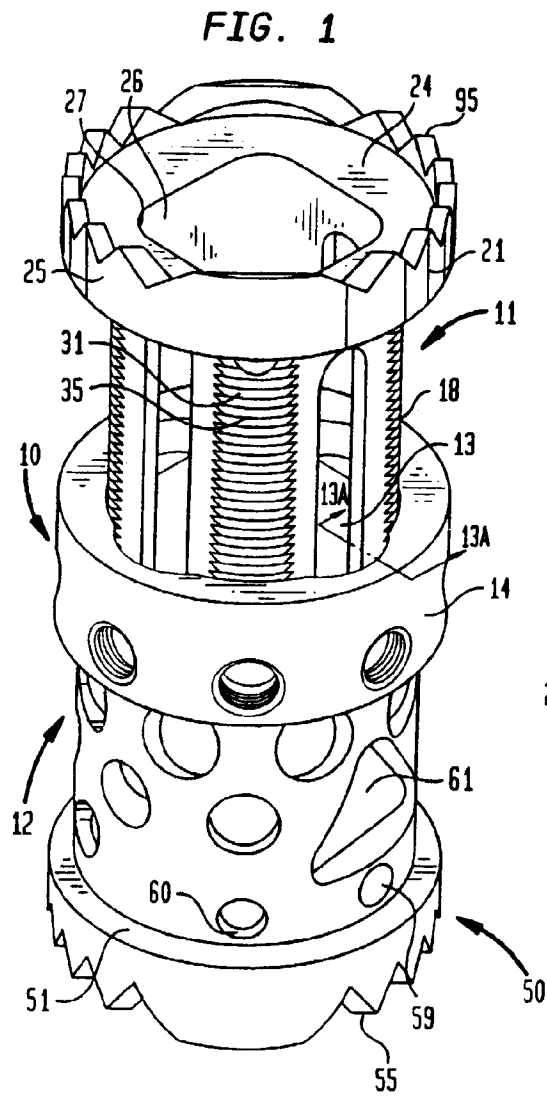


FIG. 3

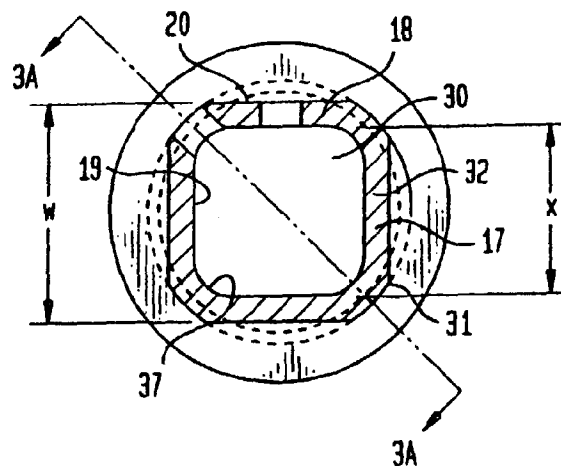


FIG. 3A

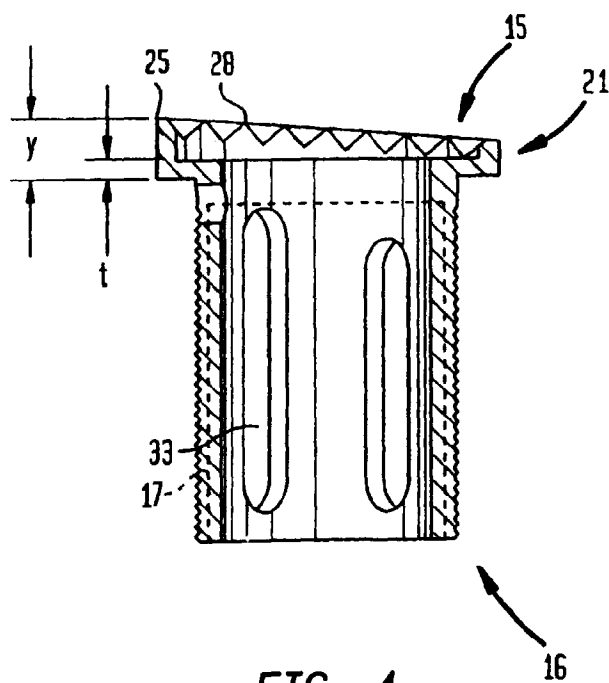


FIG. 4

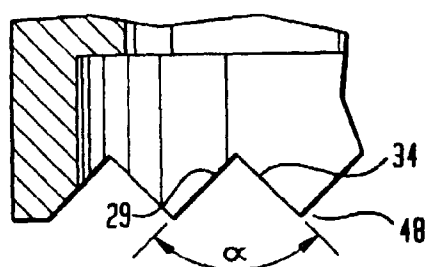


FIG. 5

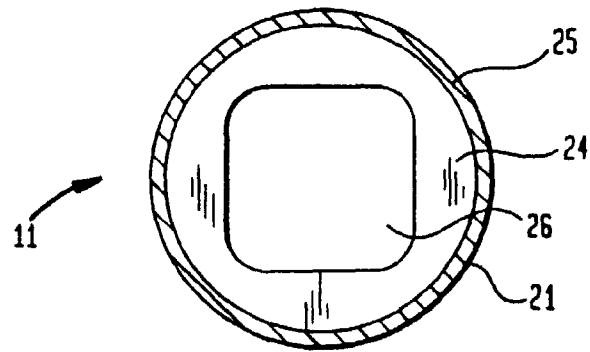


FIG. 6

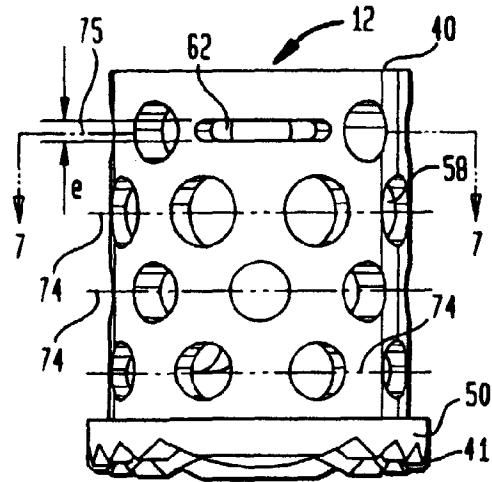


FIG. 6A

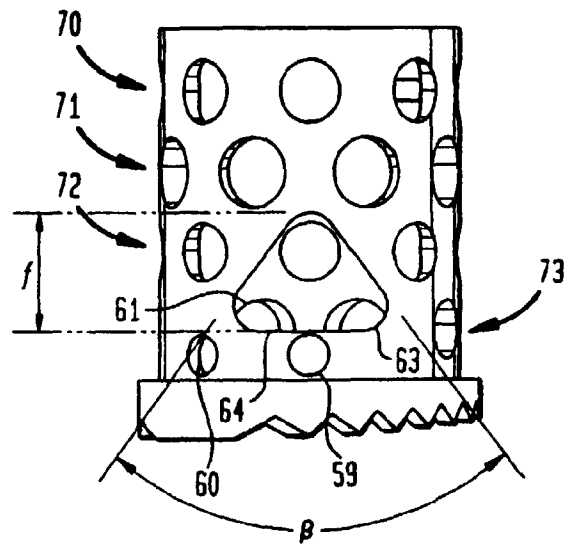


FIG. 7

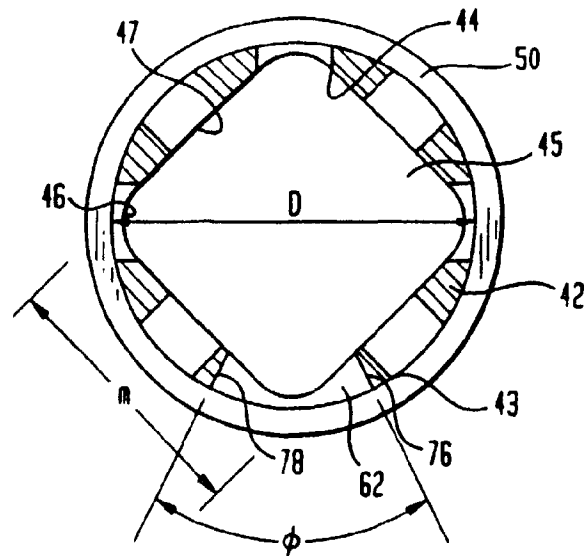


FIG. 8

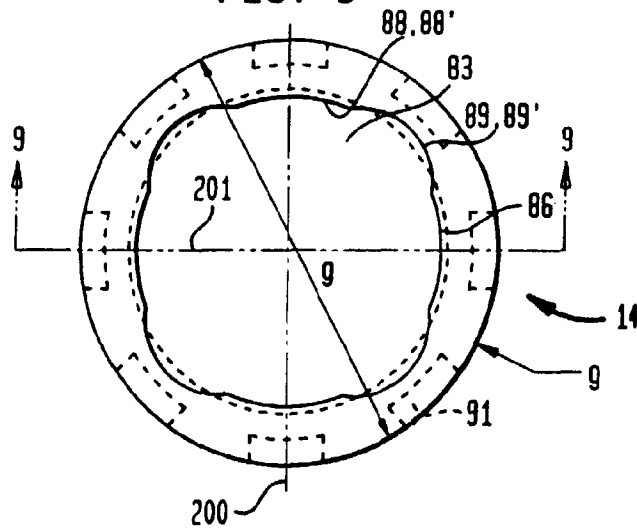


FIG. 9

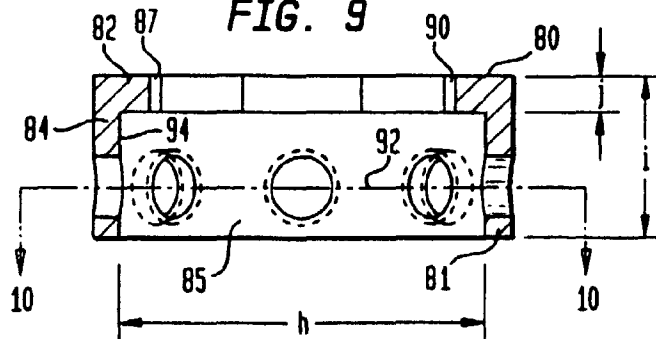


FIG. 10

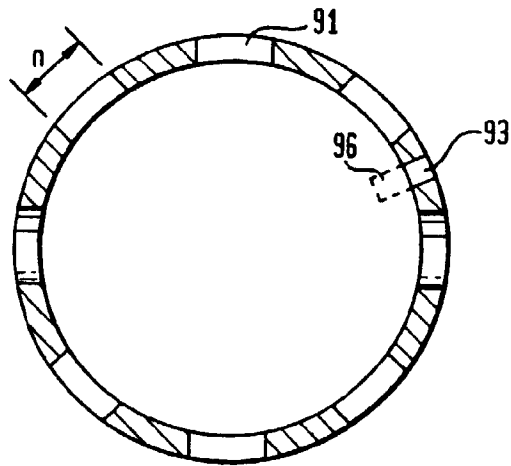


FIG. 11

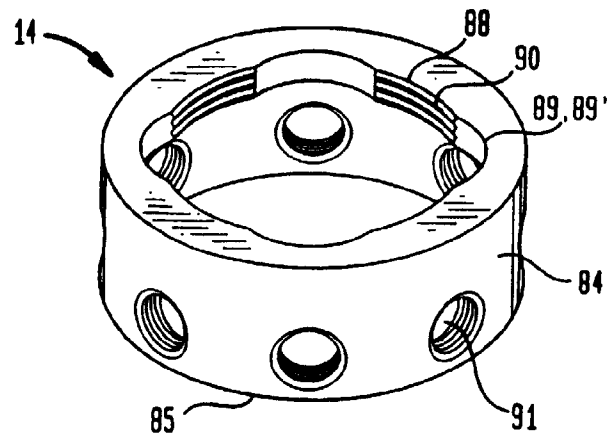


FIG. 12

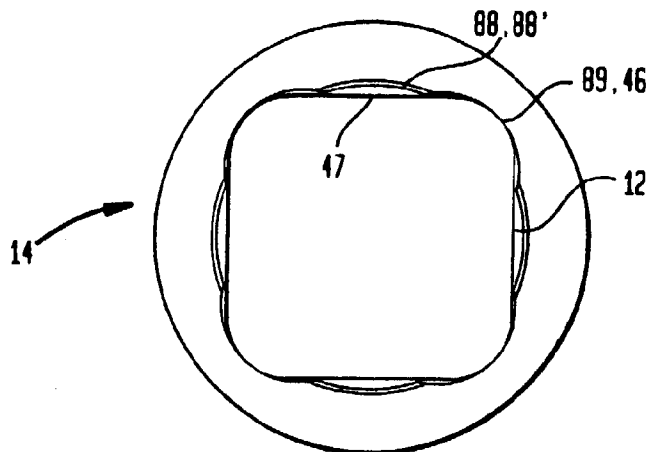


FIG. 13

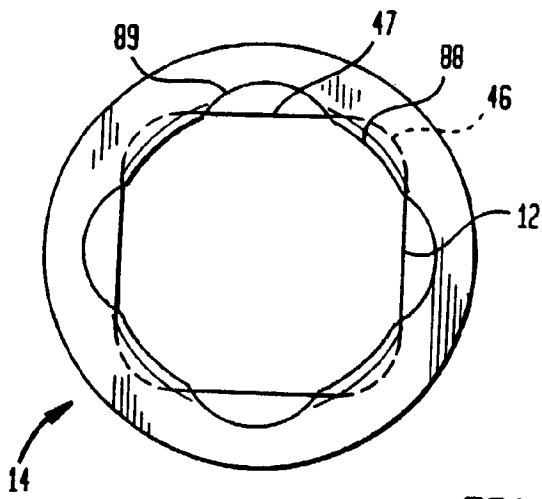


FIG. 13A

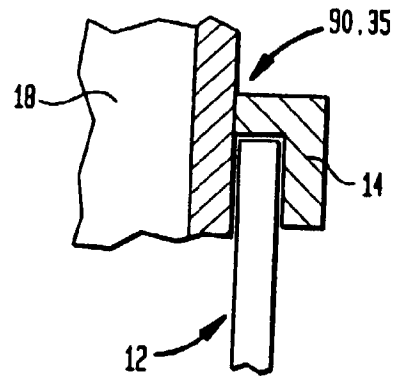


FIG. 14

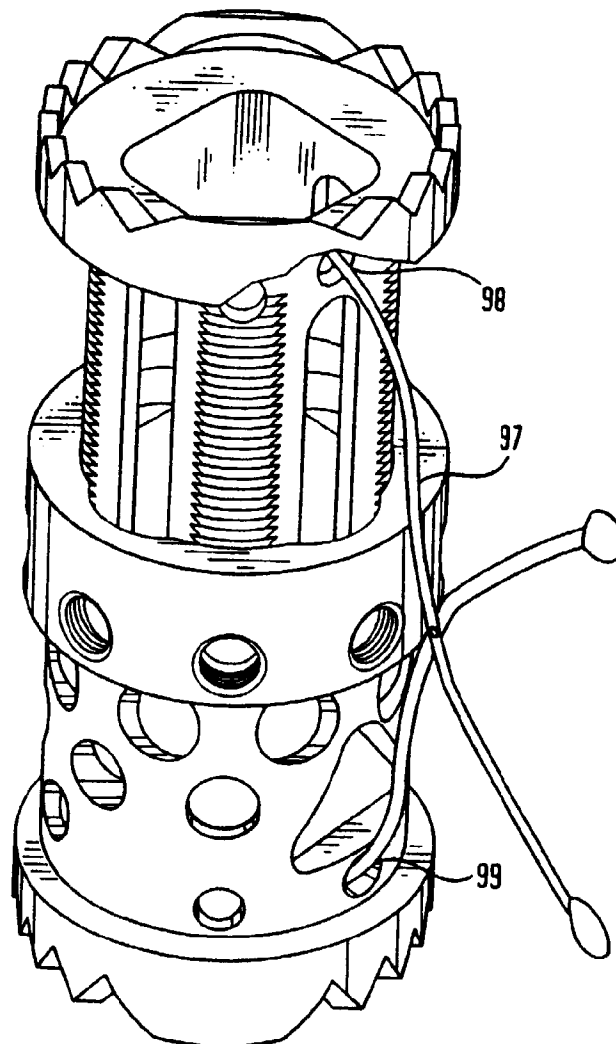


FIG. 15

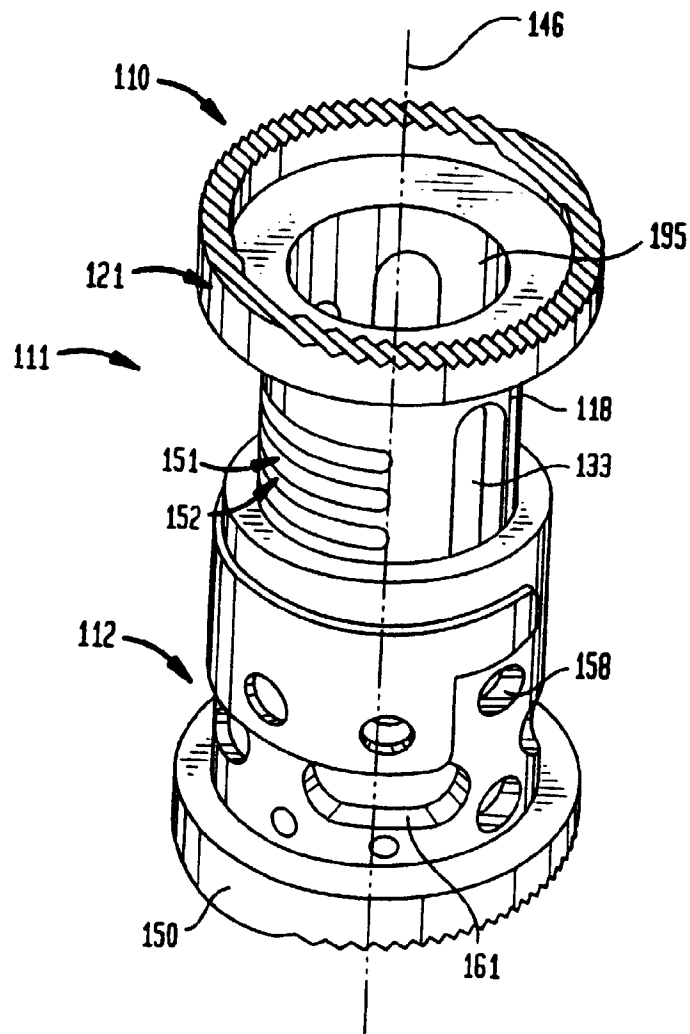


FIG. 16

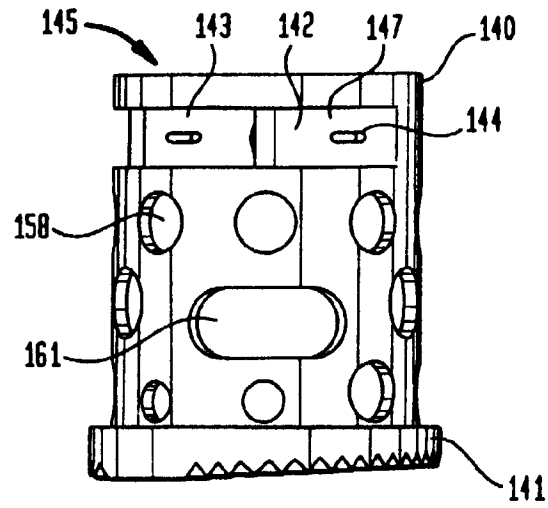
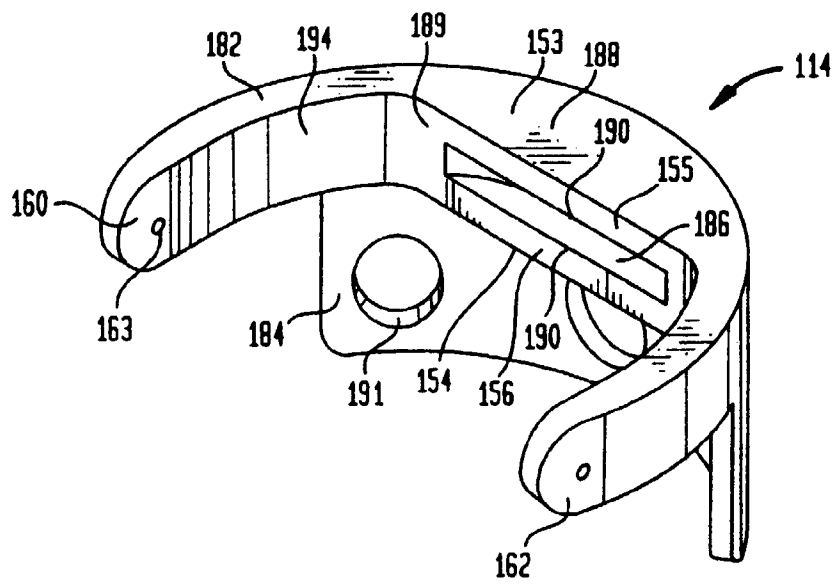


FIG. 17



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